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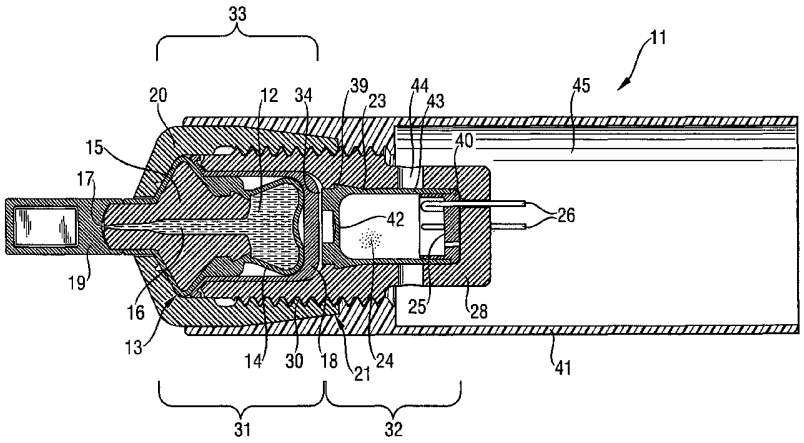
(54) Title: NEEDLELESS HYPODERMIC INJECTION DEVICE



(57) Abstract: A device for performing a needleless hypodermic injection of a liquid medication contained in a medication unit within the device. The device comprises pyrotechnical means for generating within the device a predetermined pressure value necessary for injecting the medication. The device further comprises a housing adapted to withstand by itself the predetermined internal pressure value. The housing has a first chamber which contains a medication unit storing liquid medication to be injected and a second chamber which contains a propellant container, a predetermined amount of a propellant within said propellant container, and ignition means for igniting said propellant. The medication unit has a first region and a second region that are in liquid communication with each other. The first region is deformable and the second region has an ejection outlet. The first chamber of the housing comprises two zones, a first zone containing the medication unit and a second zone which is in communication with the second chamber, so that upon ignition of the propellant in the second chamber gas generated thereby expands into the second zone of the first chamber, exerts pressure on and deforms the deformable first region of the medication unit and thereby causes ejection of the liquid medication through the ejection outlet.

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NEEDLELESS HYPODERMIC INJECTION DEVICE

FIELD OF THE INVENTION

The invention concerns a device for performing a needleless hypodermic injection of a liquid medication contained in a medication unit within the device.

The invention concerns in particular a needleless injection device which includes pyrotechnical means for generating within the device a predetermined pressure value necessary for injecting the medication.

BACKGROUND OF THE INVENTION

International Patent Application WO 98/31409 describes a hypodermic injection apparatus which comprises a body wherein a medication unit containing an amount of a medication and an activatable gas generator are arranged. Pressure generated by activation of the gas generator is applied on a deformable part of the medication unit in order to eject the medication through an outlet of the medication unit. The gas generator comprises a propellant container which contains a propellant and associated ignition means for igniting the propellant and thereby activate the gas generator. The body and the mechanical structure of the apparatus have therefore to be strong enough in order to withstand the pressure generated within the apparatus by ignition of the propellant virtually infinite number of times. To meet these requirements the device has to be constructed from high strength material with the associated volume and weight. And also training in using those systems is needed.

SUMMARY OF THE INVENTION

The instant invention is based on the discovery that a pyrotechnically driven injection device which has to withstand only one application can be constructed primarily of lightweight and low cost material.

A first aim of the invention is to provide a device of the above mentioned kind having technical features which eliminate the risk of accidental rupture of the housing of the device caused by the pressure peak which develops within the housing when a propellant is ignited within the housing in order to generate the pressure necessary to effect an injection, and which thereby provides highest security of the user against being injured due to such an accidental rupture of the housing.

A second aim of the invention is to provide a device of the above mentioned kind which in addition ensures that injections are easily and reliably performed even by a person which has received only little instruction or training.

A third aim of the invention is to provide a device of the above mentioned kind which makes use of technically relatively simple parts and which can be manufactured by simple manufacturing steps so that manufacturing cost of the device is relatively low and therefore the use of the device is economically competitive compared with use of conventional devices for performing needle injections. Under the aspects just mentioned, a particular aim of the invention is to provide an injector device the cost of which is so low that its use as a disposable or single use device is justified.

A fourth aim of the invention is to provide a design of the nozzle which is part of the medication unit of an injector device according to the invention which contributes to achieve the aim of enabling the performance of effective and reliable injections and all above mentioned aims.

According to a first aspect of the invention the above aims are achieved by means of devices defined by claims 1, 61 and 67 respectively. Claims 2 to 53, 58-60, 62-66 and 68-71 define preferred embodiments of those devices.

According to a second aspect of the invention the above aims are achieved by means of a nozzle defined by claim 54. Claims 55 to 57 define preferred embodiments of this nozzle.

The main advantages obtained with a device according to the invention are as follows:

- The design of the gas pressure generator is optimized for generating the gas pressure required to perform a needleless hypodermic injection with a very small amount of propellant. This feature makes it possible to use simple and cost effective structures for manufacturing the device. This is achieved in particular by using a pyrotechnic gas generator that is as small as possible, and has only very little heat loss.

- Protection of the user against possible injury in case of any type of failure of the device due to the inner pressure peak during the injection process is ensured by the structure of the device according to the invention, which includes a housing which is so configured and dimensioned that it is adapted to withstand an internal pressure higher than the normal injection pressure without yielding. A preferred embodiment comprises in addition a protective envelope of the housing of the device, the envelope having

the shape of a tubular layer of a tough elastic material, e.g. polyethylene.

- Very reliable operation of a device according to the invention is ensured by the provision of features which only allow the performance of an injection when some well defined conditions are satisfied.

- A particularly convenient design of the nozzle which is part of the medication unit of an injector device according to the invention contributes to achieve the above mentioned aim of the invention.

- Low manufacturing cost of a device according to the invention is achieved by the choice of suitable and low cost materials and by a device structure which optimally meets the operation, reliability and safety requirements, and which comprises a highly efficient gas generator which has a simple structure. Therefore such a device is suitable for use as a disposable or single use injector device.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject invention will now be described in terms of its preferred embodiments with reference to the accompanying drawings. These embodiments are set forth to aid the understanding of the invention, but are not to be construed as limiting.

Fig. 1 shows a schematic cross-sectional view of a first embodiment of a needleless injector module 11 according to the invention and comprising an intermediate support and a rear plug integrally formed with each other.

Fig. 2a shows a perspective cross-sectional view of the device shown by Fig. 1.

Fig. 2b shows a perspective cross-sectional and exploded view of the components of the module shown by Fig. 1.

Fig. 3a shows a module having the structure shown by Fig. 1 and shows on the right side a portion enclosed by a circle IIIb which comprises a first embodiment of a controlled bleed vent using e.g. a paper gasket.

Fig. 3b is an enlarged view of the portion IIIb shown by Fig. 3a.

Fig. 4a shows a module having the structure shown by Fig. 1 and shows on the right side a portion enclosed by a circle IVb which comprises a second embodiment of a controlled bleed vent using e.g. wax as sealing means.

Fig. 4b is an enlarged view of the portion IVb shown by Fig. 4a with the wax as sealing means before an injection is performed with the module.

Fig. 4c is an enlarged view of the portion IVb shown by Fig. 4a after wax melts and thereby opens a vent after an injection is performed with the module.

Fig. 5a is a cross-sectional view of a first propellant container which can be part of the module shown by Fig. 1.

Fig. 5b is a front view of a cap of the propellant container shown by Fig. 5a.

Fig. 5c is a cross-sectional view of the cap of the propellant container shown by Fig. 5a.

Fig. 6 is a cross-sectional view of a second propellant container which can be a part of the module shown by Fig. 1, a part of the volume of this container being filled by aerogel.

Fig. 7a is a cross-sectional view of a third propellant container which can be a part of the module shown by Fig. 1, a part of the volume of this container being filled by a pocket filled with air before ignition of the propellant.

Fig. 7b is a cross-sectional view showing the third propellant container shown by Fig. 7a during the ignition process.

Fig. 8 shows a schematic cross-sectional view of a second embodiment of a needleless injection module according to the invention and comprising as separate parts an intermediate support and a rear plug.

Fig. 9 shows an exploded cross-sectional view of the module shown by Fig. 8.

Fig. 10a shows a schematic cross-sectional view of a third embodiment of a needleless injection module according to the invention, this embodiment having a deformable zone and an O-ring seal which together form overpressure control means.

Fig. 10b shows a perspective cross-sectional view of the components of the module shown by Fig. 10a.

Fig. 10c shows a perspective cross-sectional and exploded view of the components of the module shown by Fig. 10a.

Fig. 11 shows a schematic cross-sectional view of the third embodiment shown by Fig. 10 in combination with mechanical impact ignition means.

Fig. 12 shows an enlarged view of an end part of the module shown in Fig. 11.

Fig. 13 shows a typical pressure vs. time diagram of the pressure exerted on the medication container when an injection is effected with an injector module according to the invention.

Fig. 14 shows a schematic cross-sectional view of an injector device according to the invention comprising a battery and switch mechanism for ignition.

Fig. 15 shows a schematic cross-sectional view of an injector device according to the invention comprising a battery, and a switch mechanism for ignition that includes object sensing means.

Fig. 16a shows a schematic cross-sectional view of an injector device according to the invention comprising a battery and switch mechanism for ignition that includes an interlocking object sensor function, this device being shown in a first state.

Fig. 16b shows a schematic cross-sectional view of the device shown by Fig. 16a in a second state.

Fig. 16c shows a schematic cross-sectional view of the device shown by Fig. 16a in a third state.

Fig. 17 shows a perspective exploded view of components of the object sensor interlock shown by Figures 16a to 16c.

Figures 18a to 18c show different views of a first preferred embodiment of a nozzle of the medication unit which is part of an injector module according to the invention,

Figures 19a to 19c show different views of a second preferred embodiment of a nozzle of the medication unit which is part of an injector module according to the invention.

Fig. 20 shows a schematic cross-sectional view of a fourth embodiment of a needleless injector module according to the invention.

Fig. 21 shows a schematic cross-sectional view of a fifth embodiment of a needleless injector module according to the invention.

Fig. 22 shows a schematic cross-sectional view of a sixth embodiment of a needleless injector module according to the invention.

Fig. 23 shows a schematic cross-sectional view of a seventh embodiment of a needleless injector module according to the invention.

Fig.24 shows a one-piece propellant pellet.

Figs. 25-27 show several arrays comprising several one-piece propellant pellets.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

A first, a second and a third embodiment of an injector module according to the invention, called generically

injector module 11, are first described hereinafter. This description is followed by a description of particular aspects and uses of such an injector module, including a description of an injection device comprising such an injector module.

FIRST EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

A first embodiment of a single use injector module 11 according to the invention is described hereinafter with reference to Figures 1 to 7.

As shown by Fig. 1 a single use injector module 11 according to the invention comprises components described hereinafter.

Single use injector module 11 comprises a housing 21 formed by the assembly of a pressure cell 20 and a support member 28 which is closed at one end and has also the function of a rear plug for pressure cell 20. Pressure cell 20 and a support member 28 have threads which match with each other and are thus be connected with each other by a screw connection 30.

Housing 21 is so configured and dimensioned that as a whole is adapted to withstand an internal pressure which is higher than the normal injection pressure without yielding.

Housing 21 is made preferably of a thermoplastic plastic material. A suitable housing material can be chosen e.g. from commercially available polyesters or polycarbonates taking in particular into account the mechanical properties the housing should have.

Further criteria for choosing the housing material are that it should allow relatively large dimension tolerances, that the housing should keep its original shape in order to

maintain a constant volume of the housing and to be suitable for being connected to other components simply by a snap connection 39, and that the housing material should be physiologically suitable for the intended use.

In order to ensure a safe operation of injector module 11 even if pressure within the housing accidentally exceeds a predetermined normal injection pressure, the material, shape and dimensions of the housing 21 are preferably so chosen that it has a predetermined failure zone where the housing breaks if an unduly high pressure peak arises within the housing, so as to allow gas escape from the housing in a controlled way. In a preferred embodiment housing 21 has a zone of reduced thickness (not shown in Fig. 1), which bursts so as to allow gas escape in a controlled way if an unduly high pressure peak arises within the housing, e.g. when that pressure exceeds a predetermined value.

The interior of housing 21 comprises a first chamber 31 and a second chamber 32, which are defined for instance by respective cavities of a support member 28.

A medication unit 13 is arranged within first chamber 31. A volume of liquid to be injected is stored in medication unit 13. In preferred embodiments, the amount of this volume is in a range going from about 50 to 1000 microliters. Specific examples of this amount are e.g. 200 or 500 microliters.

Medication unit 13 is a sealed medication module which comprises a nozzle body 15 and a flexible container wall 14 that hermetically encloses a portion of the nozzle and forms a reservoir 12 for a liquid medication stored in sealed medication unit 13. Wall 14 is deformable and collapsible.

Medication unit 13 thus comprises a first region and a second region that are in liquid communication with each other. The first region is deformable and comprises the reservoir enclosed by flexible wall 14. The second region of medication unit 13 comprises nozzle body 15 which has a fluid channel 16 that ends in an orifice 17 which serves as a liquid jet outlet through which liquid to be injected is ejected when an injection is performed with injector module 11. Medication unit 13 is made of suitable construction materials, e.g. polyethylene and polypropylene, which are suitable for storing medications including sensitive protein drugs.

A part of container wall 14 forms a break-off protective cap 19 that covers a jet orifice 17 of nozzle body 15. Cap 19 is removed by the user just prior to use of injector module 11.

A propellant container 23 is arranged within second chamber 32 of housing 21. Propellant container 23 contains a predetermined amount of a propellant 24. Propellant container 23 is closed by a lid 40 which carries e.g. ignition pins for electrically igniting propellant 24. When assembling injector module 11, propellant container 23 is loaded with propellant 24, e.g. in powder form, propellant container 23 is then closed by lid 40, and the so closed propellant container 23 is fitted within support member 28. As shown by Figs. 2a and 2b, lid 40 is disposed within support member 28. Support member 28 thus receives medication unit 13 and propellant container 23.

Within the scope of the instant invention a propellant is a pyrotechnic fuel which mainly contributes to the delivery of thermal energy and gas production of a pyrotechnic system and an ignition material is a pyrotechnic material used in a pyrotechnic initiator for initiating combustion of a propellant.

First chamber 31 comprises two zones, a first zone 33 which contains medication unit 13 and a second zone 34 which is located between medication unit 13 and second chamber 32. First chamber 31 is in communication with second chamber 32 so that upon ignition of propellant 24 in propellant container 23 located within second chamber 32, gas thereby generated expands into second zone 34 of first chamber 31, exerts pressure on and deforms deformable wall 14 of the first region of medication unit 13 and thereby causes ejection of the liquid medication through channel 16 and orifice 17.

In a preferred embodiment an elastic barrier 18 divides the first zone 33 from the second zone 34. The elastic barrier is made e.g. of silicon rubber, and can be reinforced e.g. with woven aramide fibers.

Support member 28 is made preferably of a rigid, plastic material which does rather break than yield when subject to mechanical stress. Support member 28 is made e.g. of thermoplastic polyester or a polycarbonate having the above mentioned properties.

As can be appreciated in particular from Fig. 2b, support member 28 has a first cavity 35 which defines part of the first chamber, a second cavity 36 which defines part of the second chamber.

In a preferred embodiment the free-volume comprised between medication unit 13 and the wall of propellant container 23 which faces medication unit 13 is much smaller than the volume of propellant container 23.

In a preferred embodiment of the single use injector module described with reference to Figures 1-4, as well as in

preferred embodiments of all other single use injection modules described with reference to the other drawings attached to this specification, housing 21 is enveloped by a tubular layer 41 which is an outer shield of injector module 11. The thickness of this layer is e.g. about 0.4 millimeter.

Tubular layer 41 is preferably made of a stretchable or compliant material which is adapted to form an outer shield which protects the user of the injector module from exhaust gas that may leak from the housing and from splinters of the housing in the event that the housing would accidentally burst due to excessive internal pressure or material failure.

Tubular layer 41 is preferably made of a polymer (e.g. polyolefine, polyolefinic acid esters, polyurethanes), in particular of polyethylene, or of soft steel, or of soft aluminum.

Propellant 24 is e.g. a fine grain nitrocellulose based composition or another nitrocellulose based composition, or another propellant composition having similar properties or a mixture of propellant compositions.

The embodiment shown by Figures 1, 2a, 2b is characterized by a seal clamping geometry which eliminates gas leaks by achieving short stress paths that minimize undesirable deflection of the components under pressure. This seal clamp geometry is particularly important when the components of the injector module are made of plastic materials, because plastic is in general much more elastic (about 30 times) than e.g. aluminum. The design shown by Figures 1, 2a, 2b makes it possible to considerably reduce deflections which would otherwise decrease system efficiency by increasing free volume, and which would cause distortions that would

make more difficult to achieve proper sealing of the injector module.

Pressure shell 20 and support member 28 in combination form a housing 21 that is a pressure vessel that carries the axial and circumferential stresses generated by the internal pressure in housing 21. The short axial stress path in the embodiment shown by Figures 1, 2a, 2b is achieved by connecting pressure shell 20 to support member 28 by a screw connection 30 close to the nozzle end of the injector module. This results in a short unidirectional axial stress path between pressure shell 20 and support member 28. Circumferential stress is resisted by the double layer consisting of the engaged threaded sections of pressure shell 20 and support member 28. With this design, a pressure shell 20 made of polycarbonate or another suitable plastic may be used without excessive deflection of housing 20 despite the inherent elasticity of the plastic material of which its components are made.

Fig. 5a shows a cross-sectional view of a first propellant container 23 which can be part of injector module 11 shown by Fig. 1. Fig. 5b shows a front view of a cap 40 of propellant container 23 shown by Fig. 5a. Fig. 5c is a cross-sectional view of cap 40.

As shown by Fig. 5a, a wall of propellant container 23 has preferably a zone 42 which has a reduced thickness. As shown by Fig. 1, this zone 42 lies between the interior of propellant container 23 and first chamber 31 shown e.g. in Fig. 1. Zone 42 is so configured and dimensioned that it bursts and thereby creates an opening when the pressure developed within propellant container 23 after ignition of propellant 24 reaches a predetermined value. In a preferred embodiment that predetermined pressure value, e.g. 100 bar, is lower than the normal injection pressure, e.g. 300 bar.

In preferred embodiments of a injector module according to the invention, propellant container 23 or at least the inner walls thereof are made of a plastic material which has a low thermal conductivity and therefore absorbs a very low amount of heat from the hot gas generated within container 23 by ignition of propellant 24, which does not show a significant chemical reaction with either the propellant or that hot gas. Such a plastic material is e.g. polyethylene or a plastic material having similar properties.

In a preferred embodiment, propellant container 23 has e.g. the structure shown by Fig. 6. In order to limit the amount of propellant 24 that can be introduced into the propellant container 23, a body 46 which contains air is introduced into propellant container 23 before filling it with propellant 24. Such a body can for instance be a pocket 47 containing aerogel material 48.

Within the scope of the instant invention an aerogel is e.g. a fine silica based low weight powder which is suitable for being used as a filler within a mixture of other chemicals, e.g. in an ignition mixture. Aerogels are e.g. low weight polymeric bodies with a 3 dimensional network, produced starting from a gel by evaporating solvent (mostly water) under appropriate conditions. The density of such aerogels is only about 3 times the density of air. Within the scope of the instant invention an aerogel can also be a solid material formed of the above mentioned aerogel in powder form that can be handled as a block in order to fill a certain volume.

Fig. 7a shows a variant of the propellant container shown by Fig. 6. In this variant the space available for propellant 24 within propellant container 23 is limited by a body which surrounds a central elongated part of propellant container

23. That body can also be a kind of pocket 47 which contains e.g. air or an aerogel material. When propellant 24 is ignited, the latter body is burned out. As shown by Fig. 7b, when this happens the volume 49 available within propellant container 23 for the gas generated is larger than the volume available for propellant 24 before ignition thereof.

Fig. 3a shows an injector module having the structure of the injector module shown by Fig. 1.

As can be appreciated from Fig. 1 and also from Fig. 3a, the embodiment represented therein is characterized in that the lateral wall of propellant container 23 has at least one safety rupture zone 43 and that the housing of the propellant container 23 has a corresponding safety vent hole 44.

In connection with the safety means just described it is important to note that propellant container 23 is made of a material which has a much lower strength than the material of support member 28 wherein propellant container 23 is lodged. Propellant container 23 has walls which are so thin that they get torn at a pressure just above the predetermined normal injection pressure which has a maximum value of e.g. 300 bars. Moreover the material of which propellant container 23 is made has a softening temperature which lies under the ignition point of the propellant. Therefore, if the injector module would happen to be subject to an unusually high environment temperature, e.g. if the injector module is unduly kept in a container exposed to sun light irradiation over a certain time, such an external heating would profoundly weaken propellant container 23 at temperatures below the propellant ignition temperature. Consequently, under the circumstances just described (device subject to unusually high environment temperature), the safety rupture zone 43 of propellant container 23 would fail

at a very low pressure and vent the gas into an attenuation volume 45 inside tubular layer 41 shown in Fig. 1.

Fig. 3a shows on the right side a portion enclosed by a circle IIIb which comprises a first embodiment of a controlled bleed vent. Fig. 3b shows an enlarged view of that portion IIIb.

As shown by Fig. 3b, the embodiment represented in Fig. 3a is characterized in that it comprises a very narrow controlled bleed vent passage 51 that leads from the inside to the outside of housing 21 such that gas within the housing is vented to atmosphere. Passage 51 comprises e.g. a vent channel 52, a vent passage 53 and a vent exit 54 around an ignition pin 26. Passage 51 has preferably a flow resistance such that flow of gas through the passage is negligible during the injection period, but vents injector module 11 to atmospheric pressure after the injection period. It should be noted that the injection period is a very short period during which the medication unit is suddenly squeezed by the injection pressure generated by ignition of propellant 24 and liquid medication thereby ejected from medication unit 13 is injected through the skin of the patient.

In a preferred embodiment passage 51 leading from the inside to the outside of propellant container 23 includes a flow resistance element 55 such that flow is negligible during an injection period of about 50 milliseconds, but vents injector module 11 to atmospheric pressure within a time interval comprised between about 10 seconds and some minutes.

In a preferred embodiment, flow resistance element 55 is a gasket based on cellulose, e.g. a paper gasket, is inserted

in at least one segment of passage 51 to form a controlled leak which vents the housing after a normal injection.

Fig. 4a shows an injector module 11 having the structure shown by Fig. 1 and shows on the right side a portion enclosed by a circle IVb which comprises a second embodiment of a controlled bleed vent using e.g. wax as sealing means. Fig. 4b is an enlarged view of the portion IVb shown by Fig. 4a with a wax layer 56 as sealing means before an injection is performed with injector module 11. Fig. 4c is an enlarged view of the portion IVb shown by Fig. 4a after wax layer 56 melts and thereby opens an annular clearance vent 57 after an injection is performed with injector module 11.

In the embodiment represented in Figures 4a to 4c a passage 57 formed around an electrically contacting ignition pin 26 contains a temperature sensitive substance such that flow through that passage 57 is blocked by the substance during the 50 millisecond injection period, and is later melted by heat generated by burning of propellant 24 and vents injector module 11 to atmospheric pressure. A temperature sensitive substance suitable for the latter purpose is e.g. a wax having a sharply defined melting point.

The embodiment described above with reference to Figures 1 to 4c has the following advantages:

- The internal volume and surface area contacted by hot propellant gas are minimized, because the components that enter into contact with hot gas are made of materials such as polyethylene and polycarbonate with low transient heat absorption. This substantially increases the thermal efficiency of injector module 11 and thereby reduces the amount of energy needed to perform an injection and thereby the amount of propellant required for that purpose. The maximum energy content of injector module 11 is thus

limited, and consequently the need for reinforcing the structure of injector module 11 with additional structure in order to handle overpressure events is reduced.

- Pressure shell 20 and support member 28 are designed to minimize the stress path length, and thereby minimize the volumetric expansion even when relatively elastic materials such as polycarbonate are used. This also makes gas sealing easier, since the seal geometry changes less under pressure. Support member 28 is preferably made of plastic to reduce losses of heat generated by ignition of the propellant gas. Pressure shell 20 does not contact the gas, and may be made of any plastic or metal with sufficient strength and ductility.

- Safety rupture zones are included in the structure of the injector module to vent gas from the inside of the structure in the event that the pressure rises significantly higher than needed for the injection. To protect the user the gas is vented into an attenuation volume 45 inside the polyethylene outer shield 41 to protect the user.

- A controlled bleed vent reduces the internal pressure to atmospheric within a few seconds to a few minutes after the injection.

- The number of components of injector module 11 is minimized, and all are designed for low-cost automated manufacture and assembly.

SECOND EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

Fig. 8 shows a schematic cross-sectional view of a second embodiment of a needleless injector module according to the

invention. Fig. 9 shows an exploded cross-sectional view of the injector module shown by Fig. 8.

This second embodiment has components which perform similar functions as in the first embodiment, but support member 28 and rear plug 29 are separate parts. This second embodiment is a viable product, it does however have longer stress paths than the first embodiment, and consequently has a higher volumetric expansion. Moreover sealing of this injector module 11 is more difficult if pressure shell 20 is made of plastic. With an aluminum pressure shell 20 volumetric expansion is lower, and a good sealing of the injector module is easier.

THIRD EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

Fig. 10a shows a schematic cross-sectional view of a third embodiment of a needleless injector module 11 according to the invention. Fig. 10b shows and a perspective cross-sectional view of the components of the device shown by Fig. 10a. Fig. 10c shows a perspective cross-sectional and exploded view of the components of injector module 11 shown by Fig. 10a.

This third embodiment has a structure similar to the structure of the second embodiment shown by Figures 8 and 9, but has in addition a deformable zone 22 and an O-ring seal 27 which together operate as vent means in case that an unduly high pressure is generated within injector module 11.

As shown by Fig. 10a, in this third embodiment support member 28 fills the space comprised between the cavities 35 and 36 (shown in Fig. 2b) and housing 21, support member has an opening 38, and housing 21 and rear plug 29 are connected with each other by means of a snap connection 58. For this

purpose housing 21 and rear plug 29 have snap grooves 62, 63 that match with each other. There is a lip seal 59 between support member 28 and pressure shell 20.

In this third embodiment the material, shape and dimensions of housing 21 are so chosen that housing 21 has at least one deformable zone 22 that rather yields than breaks in the event that the internal pressure reaches a predetermined level above the normal injection pressure, and thereby vents the housing and prevents rupture of housing 21. For this purpose housing 21 is e.g. operatively associated with means which allow venting of the housing under such circumstances. As shown by Fig. 1, housing 21 has e.g. a zone 22 of reduced thickness which cooperates with an O-ring 27 so as to allow gas escape in a controlled way if an unduly high pressure peak arises within housing 21, e.g. when that pressure exceeds a predetermined value. Such a housing thus has a wall having a zone of reduced structural strength which cooperates with sealing means adapted to yield so as to allow gas escape in a controlled way if an unduly high pressure peak arises within the housing. In other terms, in such an embodiment the assembly of housing 21 and of the components contained therein has at least one predetermined leakage zone at which a leak arises in the event that the internal pressure reaches a predetermined level above the normal injection pressure, and that leak vents housing 21 and prevents rupture thereof. In addition intermediate wall 37 of support member 28 preferably includes safety vent holes 61 shown in Fig. 10a. The venting means just described with reference to the embodiment shown by Figures 10a to 10c can also be part of the embodiment shown by Figures 8 and 9.

It should noted that in the third embodiment shown by Figs. 10a, 10b, 10c when the structure of the injector module is subject to mechanical stress due to the pressure generated within the injector module by the pyrotechnical gas pressure

generator, there is a long, bidirectional stress path leading from the nose of the pressure shell formed by housing 21 back to rear plug 29, and then forward through ignition plate 25 (shown in Fig. 10). Moreover, the circumferential pressure stress in the pressurized volume between support member 28 and pressure shell 20 forward of the O-ring seal acts with full force on pressure shell 20. Experiments have shown that the elasticity of the structure of injector module 11 in these regions causes a loss of part of the pressure generated by pyrotechnical gas pressure generator. Since a pressure shell 20 made e.g. of a suitable thermoplastic material is more deformable than a similar pressure shell made of aluminum, the pressure value generated by ignition of a given amount of propellant 24 contained in a plastic propellant container 23 is about 20 to 25% lower than the pressure value generated under similar conditions within an aluminum pressure shell.

FOURTH EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

Fig. 20 shows a schematic cross-sectional view of a fourth embodiment of a needleless injector module according to the invention.

This fourth embodiment has components which perform similar functions as in the second embodiment, but is characterized by the following features:

- An aluminum pressure shell 20 contains all other components of the injector module.
- A polyethylene propellant container 23 and an ignition plate 25 with a lip seal 116 are contained between an intermediate carrier 28 and a rear housing 29. This arrangement results in parts that are simpler to mold than the snap-fit polyethylene ignition container used in other embodiments described above.

- Propellant container has a burst membrane 42a. This membrane is a zone of the wall of propellant container 23 which has a reduced thickness, which in contrast to burst membrane 42 of other embodiments described above is thin at the edges and thick in the middle. This shape of membrane 42a is advantageous, because when the membrane burst under a sudden rise of pressure in the propellant container 23, membrane 42a swings open like a door and the entire surface of membrane 42a is suddenly open and thereby the injection pressure is fully and effectively applied to the medication unit.
- A front seal 112, an interference fit seal 113, a lip seal 114, ensure a gas-tight sealing where necessary.
- A location flange 115 ensures a proper positioning of propellant container 23.

In Fig. 20 parts similar to those of above described injector module embodiments are designated with the same reference numbers.

FIFTH EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

Fig. 21 shows a schematic cross-sectional view of a fifth embodiment of a needleless injector module according to the invention.

This fifth embodiment has components which perform similar functions as in the fourth embodiment, but is characterized by a simplified design that combines the intermediate carrier and the propellant cup into a single part 28a which is e.g. a one-piece part made by molding of a suitable plastic material, e.g. a polyester. This advantageously reduces the number of parts of the injector module and the number of gas-tight seals required. In a preferred

embodiment the latter one-piece part is made by injection molding of a polycarbonate.

In a preferred embodiment a liner containing a propellant is lodged in the propellant cup portion of the combined intermediate carrier and propellant cup 28a.

SIXTH EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

Fig. 22 shows a schematic cross-sectional view of a sixth embodiment of a needleless injector module according to the invention.

In this sixth embodiment, pressure shell 20 is a first rigid housing part which has a zone for receiving the medication unit 13. A rear housing part is a second rigid housing part which is adapted for receiving and/or carrying pyrotechnical means like a propellant and ignition means, e.g. an ignition layer and means for electrically heating the ignition layer. The first and second housing parts are connectable with each other, e.g. by a screw connection 30, and define a single chamber 118 wherein both the medication unit and the propellant are lodged. A deformable barrier 18, e.g. a rubber layer, is arranged within the latter single chamber and divides it in two zones, a first zone wherein said medication unit is located and a second zone 119 where said propellant is located. When the propellant is ignited, the pressure generated by ignition of the propellant is directly applied to deformable barrier 18 and thereby to the flexible wall 14 of medication unit for ejecting the medication contained in reservoir 12 through ejection outlet 16 of nozzle 15 of medication unit 13.

In a preferred embodiment shown by Fig. 22, this sixth embodiment has a one-piece, intermediate carrier 28b which contains a combustion chamber 118. This chamber contains

zone 119 wherein a propellant is received and lodged. In a preferred embodiment, the intermediate carrier 28b is made by molding of a plastic material, e.g. by injection molding of a polycarbonate.

In a preferred embodiment a liner containing a propellant is lodged in zone 119.

SEVENTH EMBODIMENT OF A DEVICE ACCORDING TO THE INVENTION

Fig. 23 shows a schematic cross-sectional view of a sixth embodiment of a needleless injector module according to the invention. This embodiment comprises a nozzle body 121 and a rigid housing 122 made of a plastic material. Housing 122 has a first open end adapted to receive and be connected with the nozzle body 121 and a second closed end.

The interior of the housing 122 defines a chamber which extends between the open end and the closed end of housing 122. That chamber is adapted to receive a first deformable diaphragm 123 which together with a cavity 124 of nozzle body 121 forms a medication chamber 125 suitable for receiving a predetermined amount of a medication, and a second deformable diaphragm 126 a portion of which extends around a portion of the first deformable diaphragm 123. The second deformable diaphragm 126 and the housing 122 form together a chamber for receiving a propellant 127 and means for igniting the propellant 127.

Housing 122 further contains an ignition layer 128 which is in contact with or is an integral part of the one-piece propellant pellet 127 and means for igniting the ignition layer 128. Such means include e.g. ignition pins 134 through which electrical energy is supplied to an electrical resistor used for heating the ignition layer. Ignition pins

pass through bores in the closed end of housing 122 and through bores in an ignition plate 136.

Nozzle body 121 has at its outer end an orifice 129 which is the outlet of a channel 131 for loading a liquid medication into medication chamber 125 and for ejecting the medication out of this chamber when a gas pressure generated by ignition of the propellant 127 is applied to the second deformable diaphragm 126 and thereby to the first deformable diaphragm 123.

Nozzle body 121 is made e.g. of polypropylene and the first deformable diaphragm 123 is made e.g. of polyethylene. Both polypropylene and polyethylene are materials suitable and accepted for long term storage of many medications.

In the example described with reference to Fig. 22, the amount of medication stored in medication container 124, 125 is e.g. 200 microliters.

An important characteristic of the injector structure shown by Fig. 23 is that both the medication container and the propellant are actually both contained in a single chamber. This structure minimizes heat losses and that minimizes the amount of energy and thereby the amount of propellant required to generate the gas pressure necessary for performing an injection. In the present example an amount of propellant corresponding to about 20 milligrams of a nitrocellulose based composition was used.

The orifice 129 of the nozzle body 121 is sealed by a removable foil seal 132.

In a preferred embodiment the housing 122 and the nozzle body 121 are connectable to each other by a screw connection 135.

The first deformable 123 diaphragm and nozzle body 121 are clamped together by the screw connection of housing 122 and nozzle body 121.

In another preferred embodiment the housing 122 has venting holes 133 located near to the outer edge of the first deformable diaphragm 123. In operation when propellant 127 is ignited and generates pressure, this pressure is applied to the second deformable diaphragm 126 and this diaphragm pressurizes the first deformable diaphragm and thereby the medication contained in medication container 124, 125 and causes fluid to flow into the nozzle channel 131 and be ejected as a jet through orifice 129. The space between the first diaphragm 123 and the second diaphragm 126 is vented by vents 133 to ensure that pressurized gas cannot enter into contact with the medication volume.

In a further preferred embodiment the housing 122 and the nozzle body 121 are so configured and dimensioned that they can withstand alone the pressure generated by ignition of the propellant 127.

Nozzle body 121 has preferably a tapered outer surface which has its smallest cross-section at the orifice 129 at the outer end of the nozzle body 121.

EXAMPLE OF PROPELLANT FORMS THAT CAN BE USED WITH ANY OF THE ABOVE DESCRIBED EMBODIMENTS OF A DEVICE ACCORDING TO THE INVENTION

A propellant form which can be used with any of the above described embodiments of a needleless hypodermic injection device is described hereinafter with reference to the above described seventh embodiment of such a device and with reference to Figures 23 and 24.

Fig. 23 shows an embodiment, wherein the propellant 127 is a one-piece propellant pellet. This pellet has e.g. the cylindrical or pillar shape shown by Fig. 24 and contains the main propellant charge for making an injection. The specific shape of the pellet can have features which allow to place it at a predetermined position within housing 122, e.g. for ensuring a good contact of the pellet with ignition means.

Within the scope of the invention a propellant pellet is a monolithic structure that contains one or more pre-measured pyrotechnic components. Such a pellet is handled and assembled in the gas generator as a discrete component. Use of such a propellant pellet thus eliminates the need to weigh-out and pour a propellant in powder or liquid form into a propellant container. A preferred embodiment of a propellant pellet of the kind just mentioned has zones having different properties in order to enhance the performance of the pellet. The pellet has e.g. the shape of a cylinder made of a nitrocellulose based composition and one end of this cylinder has an ignition mixture coating and this end of the cylinder is positioned next to an igniter.

Compared with prior art use of propellant in powder form, use of a one-piece propellant pellet offers the advantage of a simplification of the process for manufacturing the injection device, because the pellet comes to the process as a component having a specified weight which is simply inserted into the housing of the injection device, so that no weighing and filling machinery is necessary for handling the pellet. Propellant in powder form has on the contrary to be weighted as part of the manufacturing process and for this purpose weighing and filling machinery is necessary.

Pellets with a wide range of shapes and combinations of material are possible, providing flexibility in tailoring performance and fitting various physical configurations.

In a preferred embodiment, an ignition layer 128 is in contact with or is an integral part of the one-piece propellant pellet 127. Ignition layer 128 preferably contributes to lighting of propellant 127 and additionally provides the energy necessary for generating an initial fast rising pressure pulse.

As shown by Fig.24, propellant pellet 127 preferably has e.g. a hole 137 which extends through pellet 127 and has a star-shaped cross-section that provides an increased surface area that contributes to a rapid ignition and which provides a gas flow passage through pellet 127.

The following are examples of the chemical and structural composition of a propellant pellet 127:

Example A

Pellet 127 consists of only one grade guncotton which has been processed as a cord and which has a well defined weight per length. Cylindrical pellets 127 having predetermined dimensions and weight are obtained by cutting the cord in equidistant pieces. One end of each pellet so obtained has an ignition mixture coating. Defined positioning of the pellet into a gas generator will bring this coated end of the pellet close to an igniter.

Example B

The base material of a pellet contains a defined mixture of two varieties of guncotton with different fiber length and reactivity. This material is felt and inserted under defined conditions (weight per length / volume) into a thin tube of polyethylene having an inner diameter of e.g. 0.1 mm.

Cylindrical pellets 127 having predetermined dimensions and weight are obtained by cutting the tube into adequate cylindrical segments.
Each pellet so obtained is inserted into a gas generator and is arranged close to an igniter.

Example C

A pellet of guncotton according to example A) or example B) is produced by a method wherein additional defined amounts of other materiel like capsules of liquid are included in the pellet.

Example D

A first pellet of guncotton according to example A) or example B) is produced, but with a shorter length. A second pellet with different properties - with or without propellant properties - is set into a free space within the gas generator after having placed the first pellet within the gas generator.
The second pellet contains e.g. embedded salts, a filler (aerogel) or capsules containing a liquid. The second pellet has a whole in its center (the second pellet has a toroid-like shape) and serves as a modifier of the burning behavior of the first pellet.

A one-piece propellant pellet 127 is so manufactured that the pellet or the method for its manufacture has one or more of the following features in order to achieve desired operation characteristics:

a) Propellant pellet 127 is manufactured from a selected material, e.g. a nitrocellulose based composition, or from a combination of selected materials.
b) Propellant pellet 127 is so manufactured that it has a specified shape and mass.

c) In the process for manufacturing propellant pellets suitable ignition materials can be integrated into the propellant pellet and located at selected spots, inside the pellet or on its outer surface.

d) In the process for manufacturing propellant pellets free space between the pellet and ignition means may be provided by choice of a suitable shape of the pellet. This free space may optionally be filled e.g. with powder or with a filamentary ignition material, e.g. guncotton.

e) The pellet is a mechanical assembly of components with different properties.

f) The pellet includes aggregates of soft filamentary material such as guncotton or capsules of liquid.

g) The pellet includes geometric features such as holes or ribs to increase surface area.

h) A pellet is a structure which fits alone or combined with other pellets properly into the inner space of a gas generator, thus avoiding unduly uncontrolled displacements thereof.

i) A part of the pellet (or an additional pellet) includes a region which only acts as a spacer without propellant properties and which serves for getting the total pellet system properly fitted into the gas generator.

j) The pellet has a self-supporting structure that keeps its shape, e.g. woven, plaited or felted filamentary material structure such as guncotton.

k) The pellet has an additional cover or envelope for stabilizing the structure of the pellet, e.g. a thin tube-like or net-like mantle of e.g. polyethylene or paper-like material.

Two or more one-piece propellant pellets 127 having the same or different characteristics can be arranged within housing 122 with or without intermediate materials between them instead of a single one-piece pellet in order to achieve

particular effects like accelerating or delaying certain phases of the combustion of the propellant.

In preferred embodiments, the propellant 127 comprises an array of one-piece propellant pellets having each a predetermined shape, a predetermined chemical composition and a predetermined relative position within the array. Use of one-piece propellant pellets having different chemical compositions and therefore different burning properties make it possible to optimize the variation with time of the injection pressure generated by combustion of the propellant according to predefined criteria. Figures 25 to 27 show examples of such arrays.

Fig. 25 shows a stack 141 of cylindrical one-piece pellets 142, 143, 144. In a preferred embodiment, a hole 145 extends through the central portion of stack 141 (shown schematically).

Fig. 26 shows an array 146 of concentric cylindrical one-piece pellets 147, 148, 149. In a preferred embodiment, a hole 150extends through the central portion of array 146.

Fig. 27 shows an array 151 of one-piece pellets 152 to 157. Pellets 152 to 154 have each the shape of a segment of a cylinder having a predetermined wall thickness. Such segments are obtained by cutting a cylinder along planes parallel to the symmetry axis of the cylinder and passing through radii 158, 159, 160. Pellets 155 to 157 have each the shape of a segment of a rod having a predetermined diameter. Such segments are obtained by cutting a rod along planes parallel to the symmetry axis of the rod and passing through radii 158, 159, 160. In a preferred embodiment, a hole (not shown) extends through the central portion of array 151.

In preferred embodiments of the examples shown by Figures 25 to 27, an ignition layer is in contact with or is an integral part of an array of one-piece propellant pellets.

Propellant pellets of the above described types preferably have a coating protecting them against deterioration caused by humidity or by abrasion; in particular abrasion caused by transport, handling or storage processes.

IGNITION BY MECHANICAL IMPACT

Fig. 11 shows a schematic cross-sectional view of the third embodiment shown by Fig. 10a in combination with mechanical impact ignition means. Fig. 12 shows an enlarged view of an end part of the injector module shown in Fig. 11. The means for ignition by mechanical impact described hereinafter with reference to Fig. 11 and applied to the third embodiment shown by Fig. 10a can also be applied to the above described first and second embodiments of an injector module according to the invention.

The ignition means represented in Figures 11 and 12 comprise an impact initiated primer 72 which is hold by a primer support 73 and is adapted to be struck by a firing pin mechanism 71. Primer 72 is so positioned with respect to propellant 24 that the hot products of combustion of primer 72 ignite propellant 24.

In a preferred embodiment primer 72 and the firing pin mechanism are preferably an integral part of injector module 11 and used once and discarded.

In another preferred embodiment, primer 72 is an integral part of injector module 11 and is used once and discarded;

whereas firing pin mechanism is part of a removable module and is used more than once.

The firing pin 71 is a mechanical member that incorporates a small diameter cylindrical portion with a rounded end that strikes and indents the metal primer shell. This mechanically initiates the pyrotechnic reaction that in turn ignites propellant 24. For this purpose a flash hole 74 connects primer 72 to propellant 24. Typically pin 71 must strike with a kinetic energy of 0.1 to 0.5 joules to achieve reliable ignition. This energy is provided by a preloaded spring that accelerates the firing pin to strike the primer. Other elements in the firing pin mechanism are a trigger latch to retain the preloaded spring until it is released by the user, and a housing structure to guide the motion of the firing pin and hold the spring, trigger and firing pin in an operable relation to each other and the primer. The mechanism may be either incorporated into a disposable injector module and used once, or built into an actuation device that is attached to the injector module for actuation, and then removed and reused.

PRESSURE VS. TIME DIAGRAM

Fig. 13 shows a typical pressure (p, bar) vs. time (t, milliseconds) diagram of the injection pressure exerted on the medication container 13 when an injection is effected with an injector module 11 according to the invention. The pressure values represented are calculated on the basis of corresponding measured force values obtaining by measuring the force exerted by the ejected medication jet on a target. In the diagram of Fig. 13 the instant t = 0 is the point of time at which the pressure generated within propellant container 23 by ignition of propellant 24 is large enough to cause rupture of propellant container 23 wall that is in

face of elastic barrier 18 and establish a fluidic connection between the interior of propellant container 23 and the chamber containing the elastic barrier 18 and medication unit 13. As represented in Fig. 13 the injection pressure raises very fast, reaches a maximum value of about 300 bars in a very short time interval, a value which is suitable for producing a medication jet that pierces the patient's skin, and then slowly decreases, thereby ensuring that the entire medication volume contained in the medication container is injected.

The pressure vs. time behavior of an injector system according to the invention (represented by the diagram shown by Fig. 13) may be modified in order to modify and adjust the penetration behavior into skin and underlying tissue. This modification is preferably achieved by using a predetermined amount of a basically inert or non-energetic material that is able to exchange heat (heat transfer to and from) with the propellant gas and generate additional gas volume. This material is positioned such that it is contacted by the propellant gas in the second zone 34 of the first chamber after the propellant combustion is complete and the initial peak pressure of about 300 bars has been generated. In one embodiment, the inert material is for example a metal mesh with a defined surface to volume ratio. The initial peak pressure is little affected by the presence of this material since the heat transfer time is short. Following the initial peak pressure the temperatures of the gas and the mesh equilibrate, the mesh being heated and the gas being cooled. This results in a rapid pressure drop. As the gas expands and cools further, the sensible heat stored in the mesh flows back to the gas and sustains the gas temperature and pressure. In a second embodiment non-energetic material undergoes a simple phase change such as the vaporization of a solid or a liquid substance to gas, simultaneously absorbing heat and evolving gas. A solid to

solid or solid to liquid phase change without gas evolution is also an option. In a third embodiment the material, e.g. sodium bicarbonate, may undergo a chemical reaction such as the evolution of carbon dioxide from sodium bicarbonate while absorbing heat. In all embodiments pressure is reduced to the extent that temperature is reduced, and increased to the extent that the number of moles of gas is increased.

ELECTRICAL IGNITION MEANS

When electrical ignition means are used in the above described first, second and third embodiments of an injector module according to the invention such ignition means comprise e.g. an electrically resistive element which is brought in contact with propellant 24. The resistive element is adapted to be heated by a current provided by a source of electrical energy, e.g. a battery. The ignition means further comprise switch contacts for connecting the resistive element to the source of electrical energy.

For ensuring an effective ignition a pyrotechnic ignition material is preferably applied to the electrically resistive element. The pyrotechnic ignition material forms sparks when the resistive element is heated by the current, the sparks causing ignition of the propellant 24.

In a preferred embodiment, the resistive element, the source of electrical energy, and switch contacts are an integral part of the device, and are used only once and discarded.

In another preferred embodiment, the resistive element is an integral part of the single use injection device and is used once and discarded; but the source of electrical energy and the switch contacts are part of a removable module that is used more than once.

ADDITIONAL SECURITY AND SAFETY FEATURES

Fig. 14 shows a schematic cross-sectional view of an injector device wherein an injector module 11 according to any of the above described embodiments is arranged within a housing 81 having a grip area 82. This injector device comprises in addition a battery 83 and switch mechanism for ignition. The embodiment shown by Fig. 14 only has an actuation button 84, and does not include any object sensor. Button 84 can be displaced over a range represented by a double head arrow 87 when button 84 is actuated. For this purpose there is a sliding connection 86 between actuation button 84 and module 11. The chance of accidental actuation of the injector device is reduced by a security belt 85 that must be removed before button 84 is pressed. The security means just described are applicable to all above described embodiments of injector module.

Fig. 15 shows a schematic cross-sectional view of an injector device similar to the one shown by Fig. 14 but comprising a switch mechanism for ignition that includes an object sensor mechanism. This object sensor mechanism substantially comprises a slidable housing part 89, a spring 91 arranged as shown and a sliding connection 92 between housing 89 and module 11.
The embodiment of injector device shown by Fig. 15 must be pressed against the injection site for actuation (displacement range 93). The chance of accidental actuation is reduced by a security belt 85 that must be removed before use. This mechanism is applicable to all above described embodiments.

The reliability and security of the operation of an injector device according to the invention is increased by providing

it with an interlocking object sensor function as represented in Figures 16a, 16b, 16c and Fig. 17.

Fig. 16a is a schematic cross-sectional view of an injector device according to the invention comprising a battery and switch mechanism for ignition that includes an interlocking object sensor function which prevents use of the injector device if certain conditions are not fulfilled. Accidental use of the injector device is thereby prevented.

The provision of such an interlocking object sensor function makes sure that the injector device must first be pressed against the injection site before the actuation button can be pressed. Pressing the button first, and then applying the injector device to the injection site does not work. This mechanism is applicable to all the embodiments described above.

Fig. 16a shows a cross-sectional view of the injector device in a first state before use thereof.

Fig. 16b shows a cross-sectional view of the injector device in a second state as the injector device is pressed against the injection site, the object sensor ring is pushed back, the actuation button being thereby unlocked.

Fig. 16c shows a cross-sectional view of the injector device in a third state with the actuation button in a position at which it closes an ignition switch 103.

Fig. 17 shows a perspective exploded view of components of the object sensor interlock represented in Figures 16a to 16c.

The object sensor interlock represented in Figures 16a, 16b, 16c and Fig. 17 requires that the injector device according

to the invention be pressed against the surface at the injection site before the actuation button is allowed to be moved for carrying out the injection. The purpose of this is to increase the likelihood of a successful medication injection and reduce the chance of accidental actuation resulting in wasted medication or injury, particularly with inexperienced users.

The injector device 101 represented in Figures 16a, 16b, 16c comprises an injector module 11 according to any of the embodiments described above which contains the medication, propellant and electrical ignition means. Injector module 11 is enclosed in a structural housing 95. Two ignition conductors 26 extend from the rear of the injector module 11 and have the shape of flat metal spring members. One is structurally and electrically bonded to one terminal of a battery 83. The other is positioned so that when it is pushed by the actuation button 84 it contacts the other battery terminal. This completes the electrical circuit and enables actuation of the injector device by electrical ignition of the propellant.

Injector module 11 is rigidly connected to surrounding housing 95 through a snap joint 96 on a raised portion of the injector module 11. For performing an injection, the user grips the housing 95 to press the injection nozzle 17 against the injection site on the skin.

An object sensor ring 97 surrounds the nozzle end of the injector module 11 and is slidably mounted in an annular space between the injector module and the surrounding housing 95. The rear part of object sensor ring 97 carries fingers 98 that extend to the rear of the injector device through clearance grooves 104 (shown in Fig. 17) in the raised portion of the injector device 11.

The object sensor ring 97 and fingers 98 are urged forward by a coil spring 99. In this position the ends of the fingers 98 block motion of the actuation button 84 and prevent actuation. The other end of the spring 99 urges the actuation button 84 to the rear.

When the user presses the nozzle 17 against the skin, the object sensor ring 97 contacts the skin around the injection site and is pushed toward the rear of the injector device against the spring force. The fingers 98 are deflected inward by a surface of a cam 102 formed on the housing interior. This unlatches the actuation button 84 so that it can move far enough to push against and actuate a switch for ignition contact and thereby actuate the injector device as shown by Fig. 16c.

There is a sequential logic built into the injector device. The object sensor ring 97 must be pushed in first, and then the actuation button 84 may be pushed. If the actuation button 84 is pushed first it contacts the fingers 98, and prevents actuation by pushing on the object sensor ring 97. Neither the actuation button 84 alone nor the object sensor ring 97 alone is able to actuate the injector device.

OPTIMIZING THE INJECTION CONDITIONS BY DESIGN OF THE NOZZLE OF THE MEDICATION UNIT

Figures 18a to 18c show different views of a first preferred embodiment of a nozzle of the medication unit which is part of any of the above described embodiments of an injector module.

Figures 19a to 19c show different views of a second preferred embodiment of a nozzle of the medication unit

which is part of any of the above described embodiments of an injector module.

The design of each of these embodiments, which are preferably made of polypropylene, is based on the discovery that the details of the interaction of the liquid medication jet with the skin has an influence on the pressure required to achieve a complete injection.

The nozzle 100 shown in Figs. 18a to 18c has a flat surface 105 in contact with the skin and the minimum orifice diameter lies in the plane of this surface. This feature ensures that the fluid velocity is at a maximum when it contacts the skin.

The nozzle 100 shown in Figs. 18a to 18c has a nozzle body 15 which has a longitudinal axis which is also a rotation symmetry axis of the body. The nozzle body comprises an injection channel 16 which has a symmetry axis that coincides with the symmetry axis of the body. The end of the injection channel having a wide opening 106 is connectable to a medication container. The opposite end of the injection channel 16 is an outlet 17 for delivering medication ejected through the injection channel.

The body of the nozzle has a neck portion 107 that ends in a first end which forms a contact surface with the skin at the injection site, a basis portion 109 that ends in a second end opposite to the first end of the body, and an intermediate portion 108 that extends between the neck portion and the basis portion.

The injection channel 16 of the nozzle shown in Figs. 18a to 18c opens into an orifice 17 located at a flat top 105 of the nozzle. That orifice is in direct contact with the skin at the injection site during an injection.

Figs. 19a to 19c show a second embodiment of a nozzle 110 in which the surface in contact with the skin is a dome 111 that stretches and tensions the skin. The nozzle shown in Figs. 19a to 19c differs from the nozzle shown in Figs. 18a to 18c substantially in that the end of the nozzle body 15 which is in contact with the injection site during an injection has a rounded shape that projects towards the injection site. The minimum orifice diameter is at the peak of the dome in contact with the skin. This ensures that the skin is more easily penetrated by the liquid jet, because it is stretched and in tension.

List of reference numbers

11	injector module
12	reservoir containing liquid medication
13	medication unit
14	medication container having a flexible wall
15	nozzle body
16	fluid channel
17	orifice / jet outlet
18	elastic barrier
19	break-off protective cap
20	pressure shell
21	housing
22	deformable zone of housing 21
23	propellant container
24	propellant
25	ignition plate
26	ignition pins
27	O-ring
28	intermediate support member / intermediate support member & rear plug
28a	combined intermediate support and propellant container
28b	one-piece intermediate carrier
29	rear plug
30	screw connection
31	first chamber
32	second chamber
33	first zone of first chamber
34	second zone of first chamber
35	first cavity
36	second cavity
37	dividing wall
38	opening
39	snap connection
40	cap/lid of propellant container

41 tubular layer / outer shield
42 burst membrane / zone of reduced thickness of wall of propellant container
42a burst membrane / zone of reduced thickness of wall of propellant container
43 safety rupture zone of wall of propellant container
44 safety vent hole
45 attenuation volume inside outer shield 41
46 air containing body
47 pocket
48 aerogel material
49 volume available within propellant container
50
51 controlled bleed vent passage
52 vent channel
53 vent passage
54 vent exit
55 flow resistance element
56 wax layer
57 annular clearance vent
58 snap connection
59 lip seal
60
61 safety vent holes
62 snap grooves
63 snap grooves
64 flex finger
65
66
67
68
69
70
71 firing pin
72 impact initiated primer

73 primer support
74 flash hole
75
76
77
78
79
80
81 housing
82 grip area
83 battery
84 actuation button
85 security belt
86 sliding connection
87 displacement range
88
89 housing
90
91 spring
92 sliding connection
93 displacement range
94
95 housing
96 snap joint
97 object sensor ring
98 interlock fingers
99 coil spring
100 nozzle
101 injector device
102 cam
103 switch for ignition contact
104 finger clearance grooves
105 flat surface of nozzle
106 opening of nozzle
107 neck portion of nozzle
108 intermediate portion of nozzle

109 basis portion of nozzle
110 nozzle
111 domed top surface of nozzle
112 front seal
113 interference fit seal
114 lip seal
115 location flange
116 lip seal
117
118 single chamber
119 propellant receiving zone
120
121 nozzle body
122 housing
123 deformable diaphragm
124 cavity
125 medication chamber
126 deformable diaphragm
127 propellant / propellant pellet
128 ignition layer
129 orifice
130
131 injection channel
132 removable foil seal
133 venting hole
134 ignition pins
135 screw connection
136 ignition plate
136
137 hole in propellant pellet 127
138
139
140
141 stack of one-piece propellant pellets
142 one-piece propellant pellet
143 one-piece propellant pellet

144 one-piece propellant pellet
145 hole extending through propellant pellets 141-143
146 array of concentric cylindrical one-piece propellant pellets
147 one-piece propellant pellet
148 one-piece propellant pellet
149 one-piece propellant pellet
150 hole
151 array one-piece propellant pellets
152 one-piece propellant pellet
153 one-piece propellant pellet
154 one-piece propellant pellet
155 one-piece propellant pellet
156 one-piece propellant pellet
157 one-piece propellant pellet
158 radius
159 radius
160 radius

Although a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

Claims

1. A device for performing a needleless hypodermic injection of a liquid medication contained in a medication unit within the device, said device including pyrotechnical means for generating within the device a predetermined pressure value necessary for injecting the medication, said device comprising

(a) a housing which is so configured and dimensioned that it is adapted to withstand or uptake alone, i.e. by itself, said predetermined internal pressure value

(b) a first chamber within said housing, said first chamber containing a medication unit configured and dimensioned to store a volume of liquid medication to be injected, said medication unit having a first region and a second region that are in liquid communication with each other, said first region being deformable and said second region having an ejection outlet, and

(c) a second chamber within said housing, said second chamber containing a propellant container, a predetermined amount of a propellant within said propellant container, and ignition means for igniting said propellant,

said first chamber comprising two zones, a first zone containing said medication unit and a second zone which is in communication with said second chamber, so that upon ignition of the propellant in the second chamber gas generated thereby expands into said second zone of said first chamber, exerts pressure on and deforms said deformable first region of said medication unit and thereby causes ejection of said liquid medication through said ejection outlet.

2. A device according to claim 1, wherein said housing has at least one deformable zone that yields in the event that the internal pressure reaches a predetermined value above said normal injection pressure, and thereby vents said housing and prevents rupture of the housing.

3. A device according to claim 1, wherein said housing is partially or entirely made of a deformable plastic material.

4. A device according to claim 1, wherein said housing is made of a metal.

5. A device according to claim 1, wherein said part is made of aluminum or steel

6. A device according to claim 1, characterized in that it is a single use, disposable device.

7. A device according to claim 1, wherein a wall of said housing has a zone of reduced structural strength which cooperates with sealing means adapted to yield so as to allow gas escape in a controlled way if an unduly high pressure peak arises within the housing.

8. A device according to claim 1, wherein the assembly of said housing and of the components contained therein has at least one predetermined leakage zone at which a leak arises in the event that the internal pressure reaches a predetermined level above said normal injection pressure, and thereby vents said housing and prevents rupture of the housing.

9. A device according to claim 1, wherein said housing has a predetermined failure zone where the housing breaks if

an unduly high pressure peak arises within the housing, so as to allow gas escape from the housing in a controlled way.

10. A device according to claim 1, wherein a lateral wall of propellant container 23 has at least one safety rupture zone 43 and that a housing of the propellant container 23 has a corresponding safety vent hole.

11. A device according to claim 1, wherein said housing is made of a polycarbonate.

12. A device according to claim 1, wherein said propellant chamber has a wall which before ignition of the propellant serves as a dividing wall between a first cavity in said first chamber and a second cavity in said second chamber.

13. A device according to claim 1, wherein said housing contains a support member which has

a first cavity which defines part of said first chamber,

a second cavity which defines part of said second chamber, and

a dividing wall which separates said first cavity from said second cavity, said wall having an opening which allows flow of a gas from one of said cavities to the other,

said support member filling the space comprised between said cavities and said housing.

14. A device according to claim 13, wherein said support member is made of a rigid, plastic material which does rather break than yield when subject to mechanical stress.

15. A device according to claim 14, wherein said support member is made of a polycarbonate.

16. A device according to any of claims 12-15, wherein the volume of space comprised between said medication unit and said dividing wall of said support member is much smaller than the volume of said propellant container.

17. A device according to any of the preceding claims, wherein said housing is enveloped by a tubular layer.

18. A device according to claim 17, wherein said tubular layer is made of a stretchable or compliant material which is adapted to form an outer shield which protects the user of the device from exhaust hot gas that may leak from the housing and from splinter of the housing in the event that the housing would accidentally burst due to excessive internal pressure and/or material failure.

19. A device according to any of claims 17 or 18, wherein said tubular layer is made of a polymer, in particular of polyethylene, or of soft steel, or of soft aluminum.

20. A device according to any of claims 17 or 18, wherein said tubular layer is made of a tough elastic material that is resistant against common cleaning and disinfecting liquids.

21. A device according to any of claims 17 or 18, wherein said tubular layer has a two layer structure comprising an outer tubular layer and an inner tubular layer, said outer layer being made of a tough elastic material that is resistant against common cleaning and disinfecting liquids, and said inner layer being a sponge like, porous layer material made of the same material as the outer layer or of a compound material.

22. A device according to any of claims 17 to 21, wherein said tubular layer has a thickness of about 0.4 millimeter

23. A device according to any of the preceding claims , wherein a wall of said propellant container has a zone of reduced thickness which lies between the interior of the propellant container and said first chamber, said zone of reduced thickness being so configured and dimensioned that it bursts and thereby creates an opening when the pressure developed within the propellant container after ignition of the propellant reaches a predetermined value, said predetermined value being lower than a maximum pressure value necessary for injecting the medication.

24. A device according to claim 23, wherein said propellant container or at least the inner walls of said propellant container are made of a plastic material which has a low thermal conductivity and therefore absorbs a very low amount of heat from the hot gas generated within container by ignition of propellant, which is not able to chemically react with either the propellant or with that hot gas to any significant extent.

25. A device according to claim 24, wherein said plastic material is a polyoleofine.

26. A device according to claim 24, wherein said plastic material is polyethylene.

27. A device according to any of the preceding claims, wherein said propellant container comprises limiting means for limiting the amount of propellant that can be introduced into the propellant container.

28. A device according to claim 27, wherein said limiting means are an aerogel.

29. A device according to claim 27, wherein said limiting means is an air filled bag of polyethylene or a similar material.

30. A device according to any of the preceding claims, said propellant is a nitrocellulose based composition or another propellant having similar gas generating properties.

31. A device according to any of the preceding claims, wherein an elastic barrier divides said first zone from said second zone.

32. A device according to claim 31, wherein said elastic barrier is reinforced with woven fibers in order to increase its resistance against rupture.

33. A device according to claim 32, wherein said fibers are aramide fibers.

34. A device according to claim 32, wherein said fibers are nylon fibers.

35. A device according to claim 1 wherein said ignition means comprise an electrically resistive element which is brought in contact with said propellant, said resistive element being adapted to be heated by a current provided by a source of electrical energy.

36. A device according to claim 35, wherein pyrotechnic ignition material is applied to said electrically resistive element, said material thereby chemically reacting and generating heat and hot particles when said resistive element is heated by said current, said generated heat and hot particles causing ignition of said propellant.

37. A device according to claim 35, wherein said resistive element, said source of electrical energy, and switch contacts are an integral part of said device, and are used only once and discarded.

38. A device according to claim 35, wherein said resistive element is an integral part of said device and used once and discarded; and said source of electrical energy, and switch contacts are part of a removable module and used more than once.

39. A device according to claim 1, wherein said ignition means comprise an impact initiated primer struck by a firing pin mechanism, said primer being so positioned with respect to said propellant that the hot products of combustion of said primer ignite said propellant.

40. A device according to claim 39, wherein said primer and said firing pin mechanism are an integral part of said device and used once and discarded.

41. A device according to claim 39, wherein said primer is an integral part of said device and used once and discarded; and said firing pin mechanism is part of a removable module and used more than once.

42. A device according to claim 1, wherein the outer end of said injection outlet is pressed against the patient's skin to open an interlock and enable actuation by the user.

43. A device according to claim 42, wherein a sliding ring surrounds said outer end of said injection outlet, and is biased toward said outer end, such that when said sliding ring is pressed against said patient's skin, said interlock is opened.

44. A device according to claim 42, wherein said device is movably mounted on a base and is biased toward said outer end of said injection outlet, such that when said outer end of said injection outlet is pressed against said patient's skin, said interlock is opened.

45. A device according to claim 1, wherein a passage leads from the inside to the outside of said housing such that gas within said housing is vented to atmosphere.

46. A device according to claim 45, wherein said passage has a flow resistance such that flow is negligible during the injection period, but vents the device to atmospheric pressure after said injection period.

47. A device according to claim 45, wherein a passage leading from the inside to the outside of the propellant chamber includes a flow resistance element such that flow is negligible during an injection period of about 50 milliseconds, but vents the device to atmospheric pressure within a time interval comprised between about 10 seconds and some minutes.

48. A device according to claim 45, wherein said passage contains a temperature sensitive substance such that flow is blocked during the 50 millisecond injection period, and later melts from propellant heat to vent the device to atmospheric pressure.

49. A device according to claim 48, wherein said temperature sensitive substance is a wax with a sharply defined melting point.

50. A device according to claim 45, wherein a gasket based on cellulose or a paper gasket is inserted in that passage

to form a controlled leak which vents the housing after a normal injection.

51. A device according to claim 1, wherein said second zone of said first chamber of said housing contains a predetermined amount of a basically non-energetic material which is able to interact with hot gas generated by ignition of the propellant, and which thereby influences the variation of the temperature and the pressure of said hot gas in said second zone.

52. A device according to claim 51, wherein said interaction is a thermal interaction of said material with said hot gas.

53. A device according to claim 51, wherein said interaction produces additional gas generated by the interaction of said material with said hot gas.

54. A nozzle which is part of a medication unit of a device according to claim 1,

said nozzle having a body having a longitudinal axis which is also a rotation symmetry axis of said body,

said body comprising an injection channel having a symmetry axis that coincides with said symmetry axis of said body,

said injection channel having at a first end thereof an inlet connectable to a medication container, said injection channel having at a second end thereof opposite to said first end an outlet for delivering medication ejected through said injection channel, and

said body having a neck portion that ends in a first end which forms a contact surface with the skin at the injection site, a basis portion that ends in a second end opposite to said first end of said body, and an intermediate

portion that extends between said neck portion and said basis portion.

55. A nozzle according to claim 54, characterized in that it is made of polypropylene.

56. A nozzle according to claims 54 or 55, characterized in that said injection channel opens into an orifice located at a flat top of the nozzle, said orifice being in direct contact with the skin at the injection site during an injection.

57. A nozzle according to claims 54 or 55, wherein the first end of the nozzle body has a rounded shape that projects towards the injection site.

58. A device according to claim 13, wherein said support member and said propellant container are integrally built as a single part.

59. A device according to claim 13, wherein said support member and said propellant container are integrally built by molding of a plastic material.

60. A device according to claim 59, wherein a liner containing a propellant is arranged within said propellant container.

61. A needleless hypodermic injection device for injecting a liquid medication comprising

(a) a nozzle body,

(b) a rigid housing,

said housing having

a first open end adapted to receive and be connected with the nozzle body and a second closed end,

the interior of said housing defining a chamber which

extends between said open end and said closed end of the housing, said chamber being adapted to receive

a first deformable diaphragm which together with a cavity of said nozzle body forms a medication chamber suitable for receiving a predetermined amount of a medication, and

a second deformable diaphragm a portion of which extends around a portion of said first deformable diaphragm,

said second deformable diaphragm and said housing forming together a chamber for receiving a propellant and means for igniting said propellant,

said nozzle body having at its outer end an orifice which is the outlet of a channel for loading a liquid medication into the medication chamber and for ejecting said medication out of said chamber when a gas pressure generated by ignition of said propellant is applied to said second deformable diaphragm and thereby to said first deformable diaphragm.

62. A device according to claim 61, wherein the orifice of the nozzle body is sealed by a removable foil seal.

63. A device according to claim 61, wherein said housing and said nozzle body are connectable to each other by a screw connection.

64. A device according to claim 61, wherein said housing has venting means located near to the outer edge of said first deformable diaphragm.

65. A device according to claim 61, wherein said housing and said nozzle body are so configured and dimensioned that they can withstand alone the pressure generated by ignition of the propellant.

66. A device according to claim 61, wherein said nozzle body has a tapered outer surface which has its smallest cross-section at the orifice at the outer end of the nozzle body.

67. A device for performing a needleless hypodermic injection of a liquid medication contained in a medication unit within the device, said device including pyrotechnical means for generating within the device a predetermined pressure value necessary for injecting the medication, said device comprising

(a) a medication unit for storing a volume of liquid medication to be injected, said medication unit having a first region and a second region that are in liquid communication with each other, said first region being deformable and said second region having an ejection outlet,

(b) a first rigid housing part having a first zone for receiving said medication unit,

(c) a second rigid housing part for receiving and/or carrying said pyrotechnical means,

said first and second housing parts being connectable with each other and defining a single chamber, and

(d) a deformable barrier arranged within said single chamber and dividing said chamber in two zones, a first zone wherein said medication unit is located and a second zone where said propellant is located,

pressure generated by combustion of said propellant being directly applied to said deformable barrier and thereby to said deformable region of said medication unit for ejecting said medication through said ejection outlet of said second region of said medication unit.

68. A device according to any of claims 1 to 67, wherein said propellant is a one-piece propellant pellet.

69. A device according to claim 68, wherein an ignition layer is in contact with or is an integral part of said one-piece propellant pellet.

70. A device according to any of claims 1 to 67, wherein said propellant is an array of one-piece propellant pellets having each a predetermined shape, a predetermined chemical composition and a predetermined relative position within the array.

71. A device according to claim 70, wherein an ignition layer is in contact with or is an integral part of said array of one-piece propellant pellets.

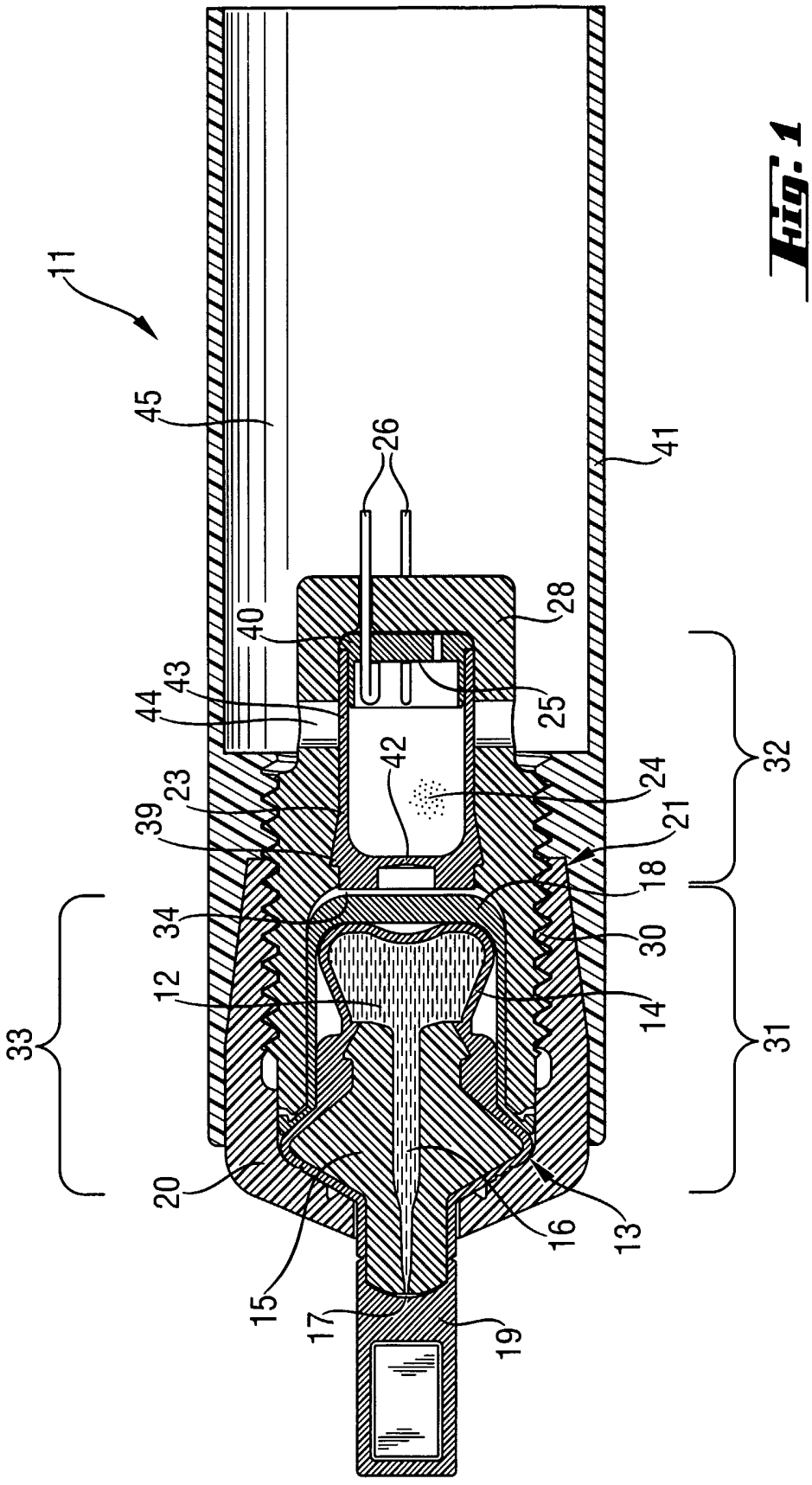
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Fig. 1

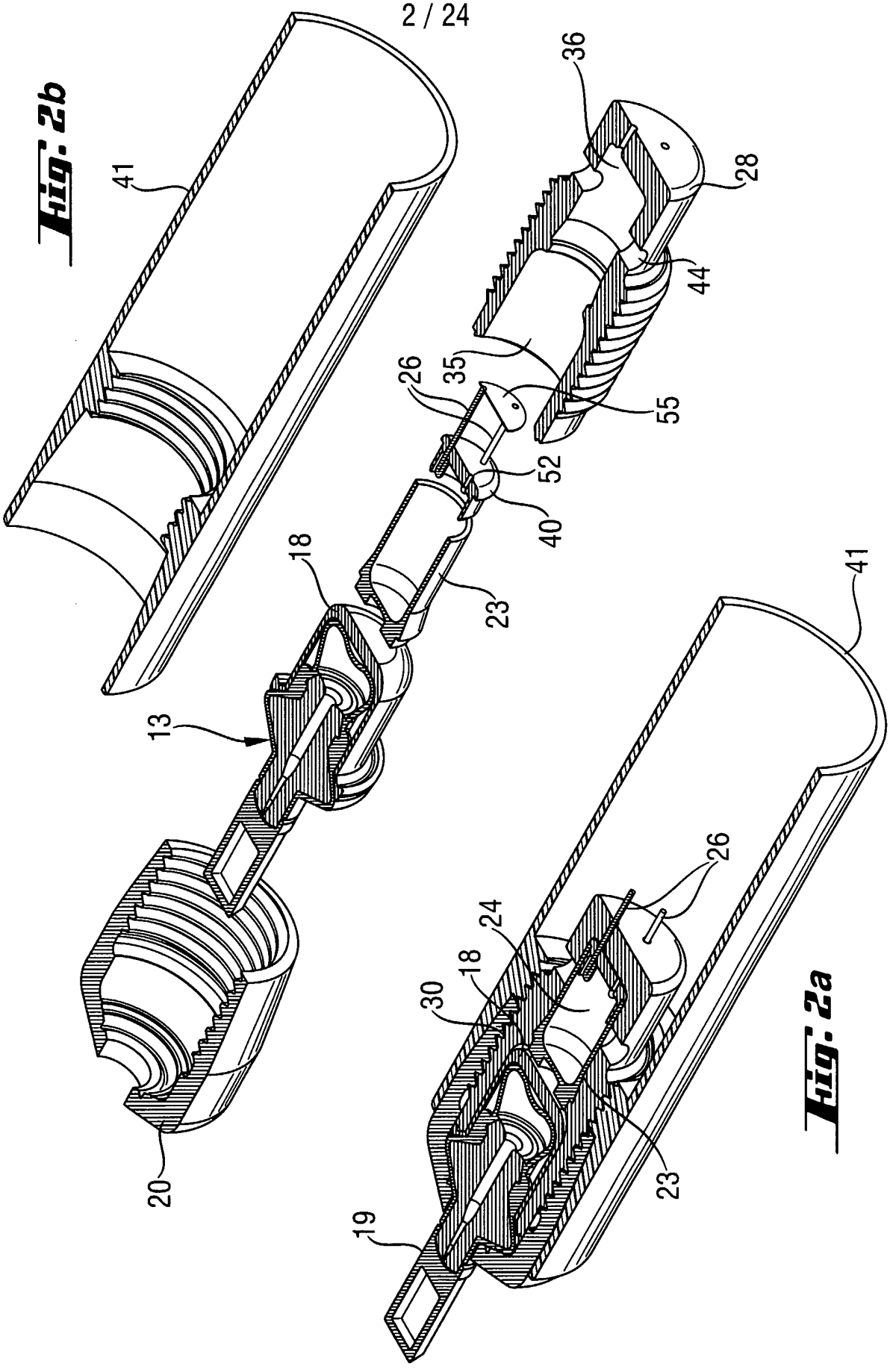
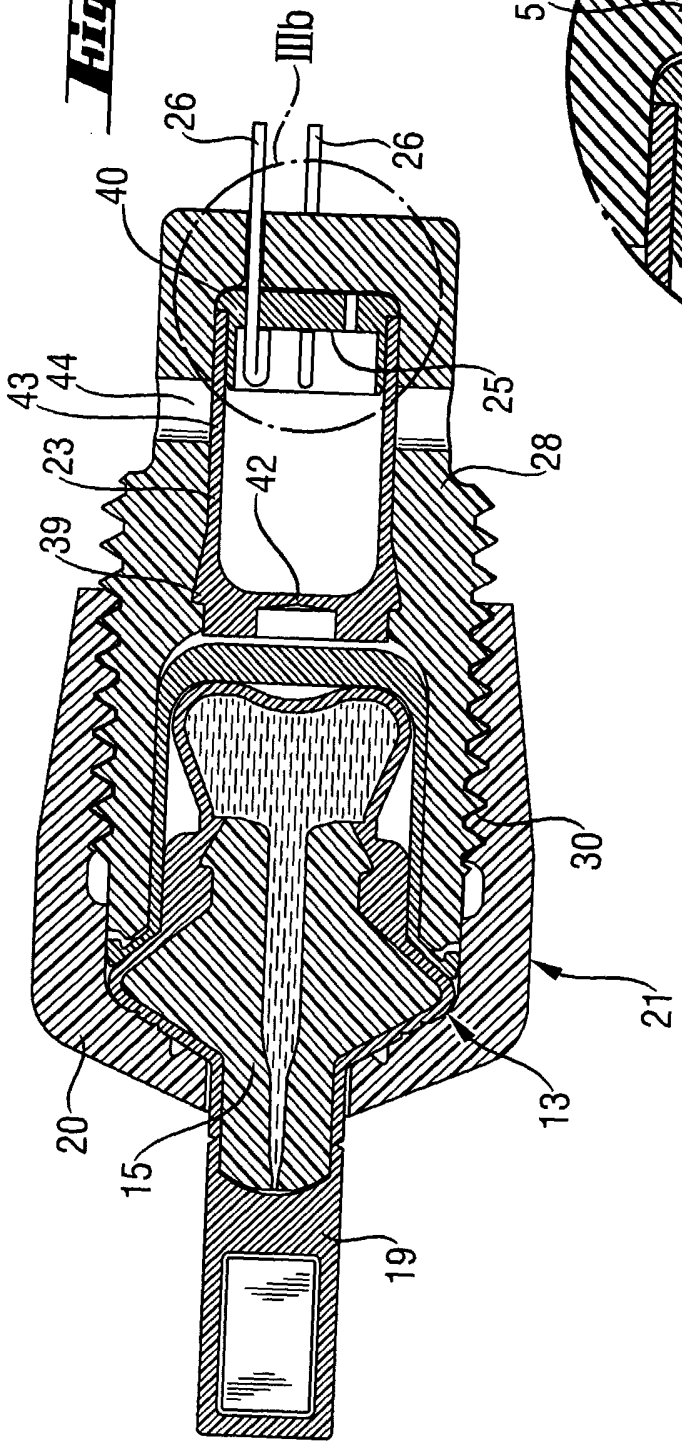


Fig. 2b

Fig. 2a

Fig. 3a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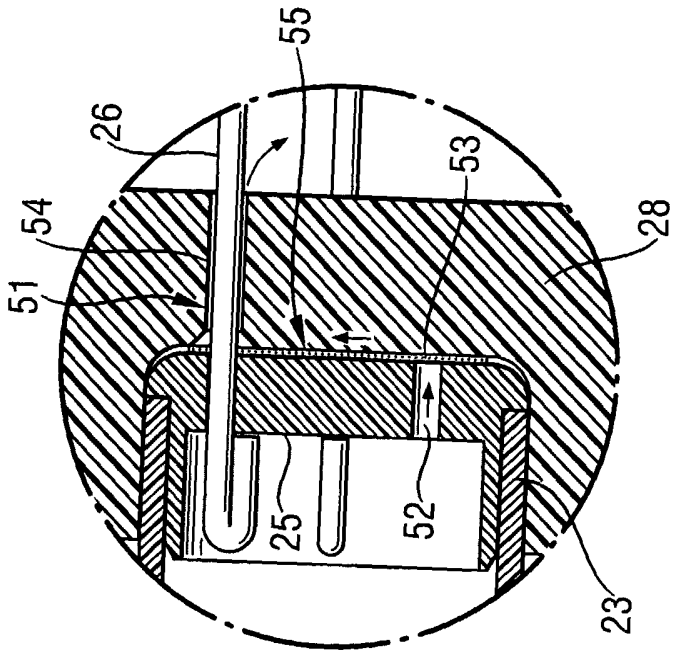
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Fig. 3b

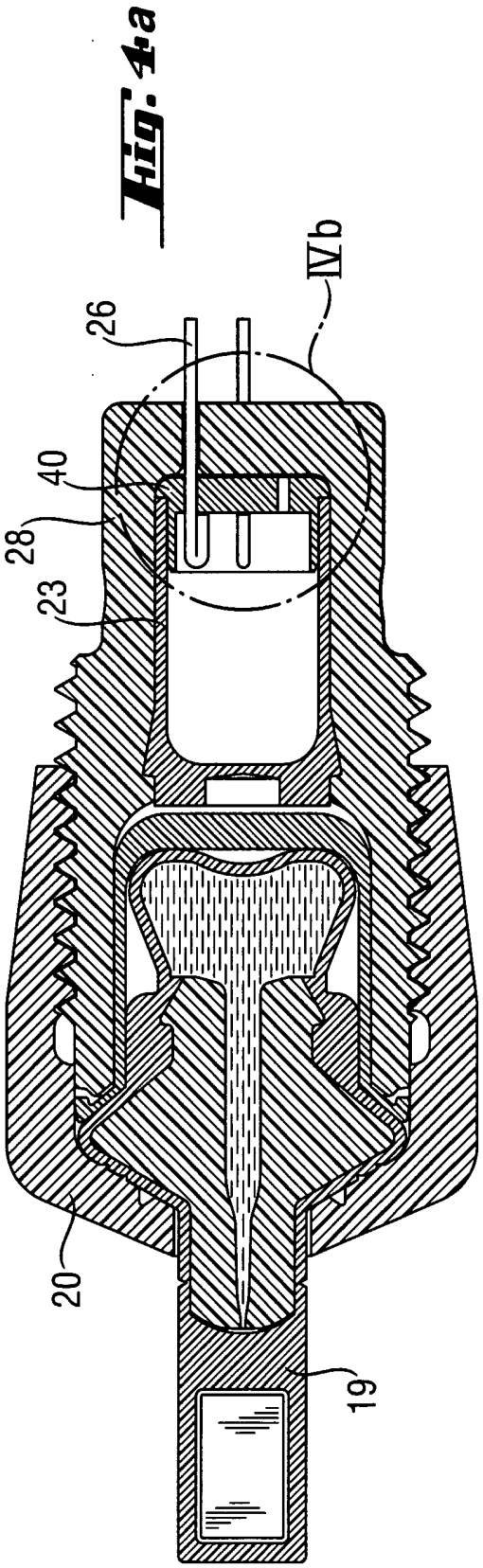


Fig. 4a

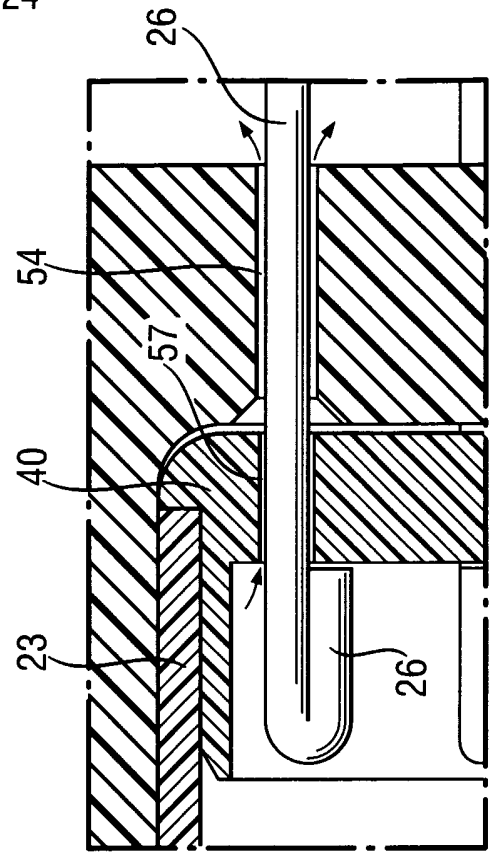


Fig. 4c

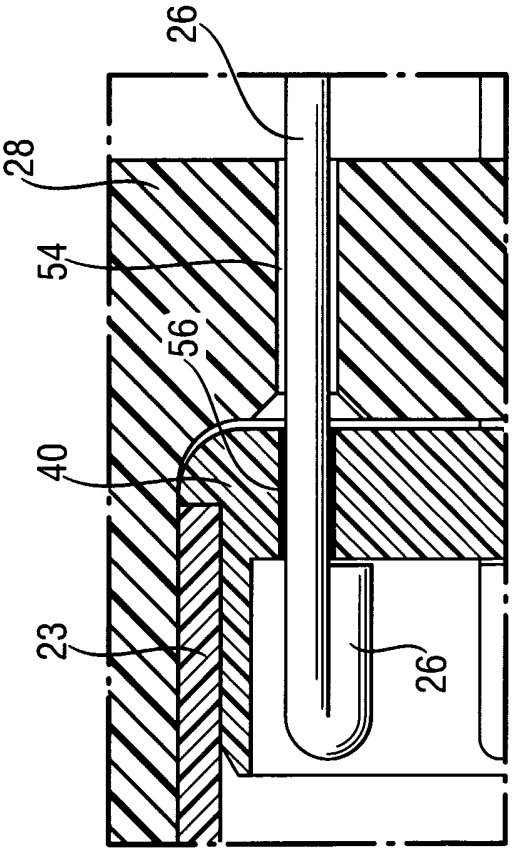


Fig. 4b

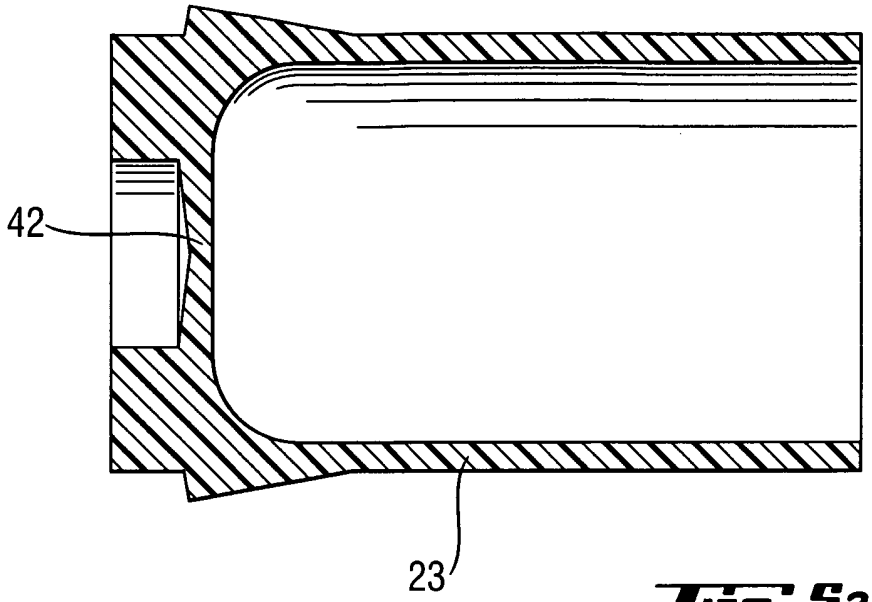


Fig. 5a

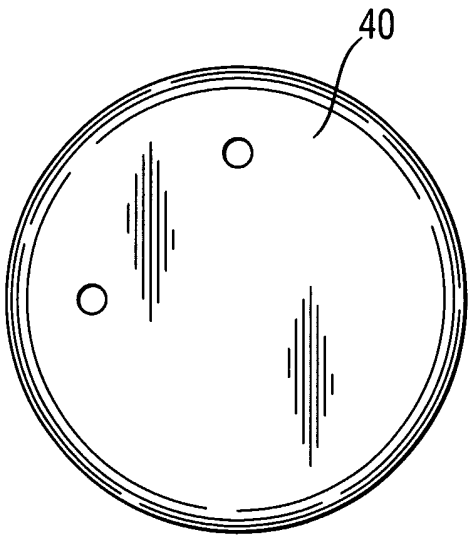


Fig. 5b

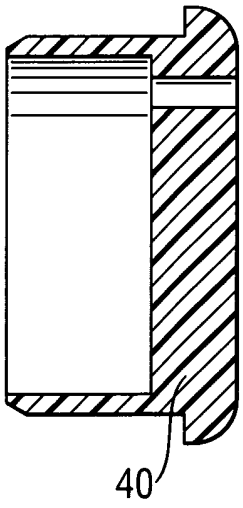


Fig. 5c

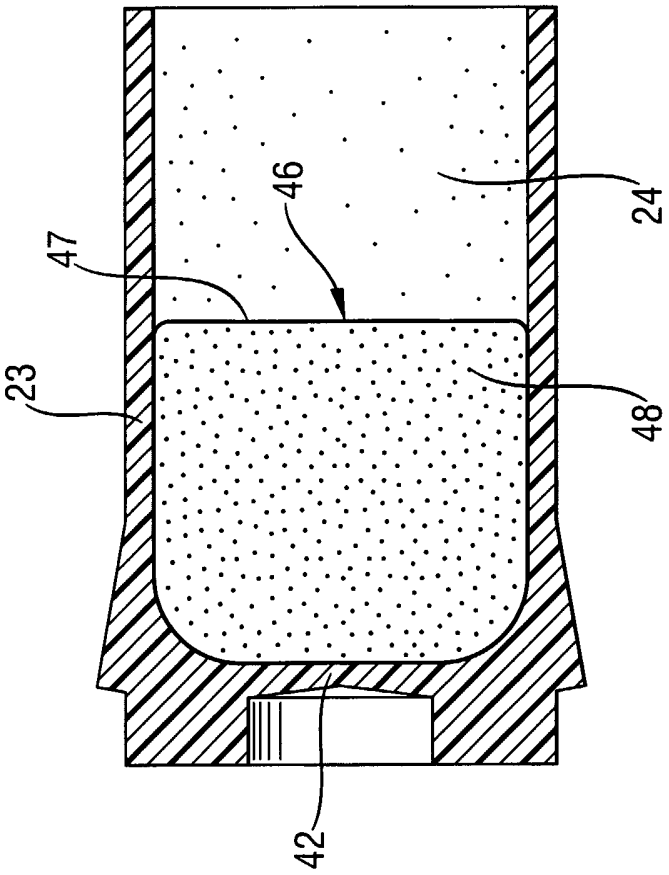


Fig. 6

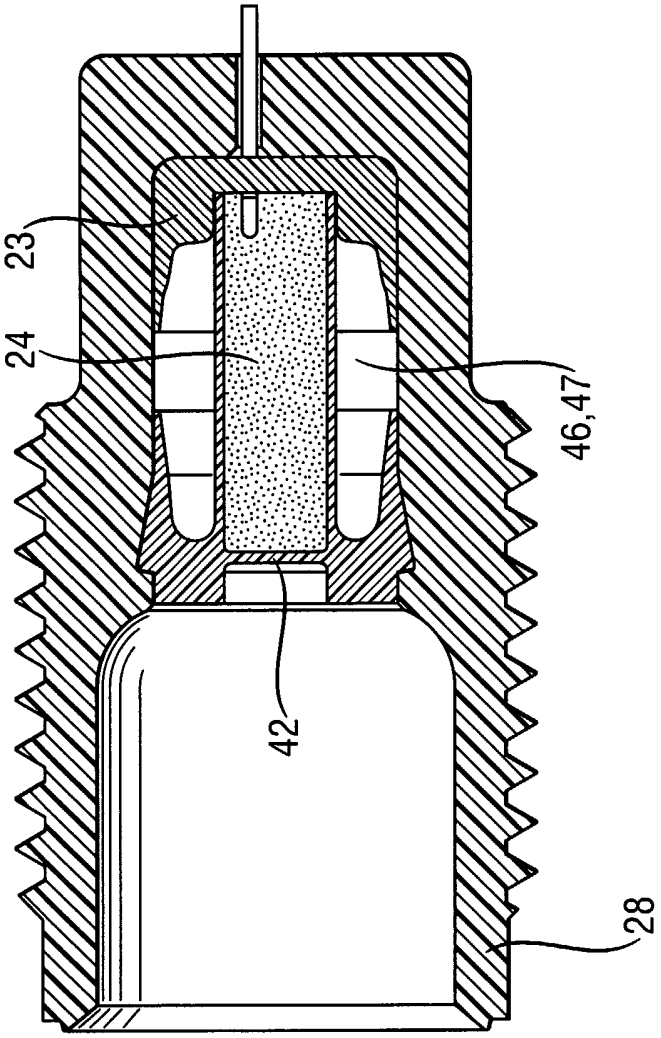


Fig. 1a

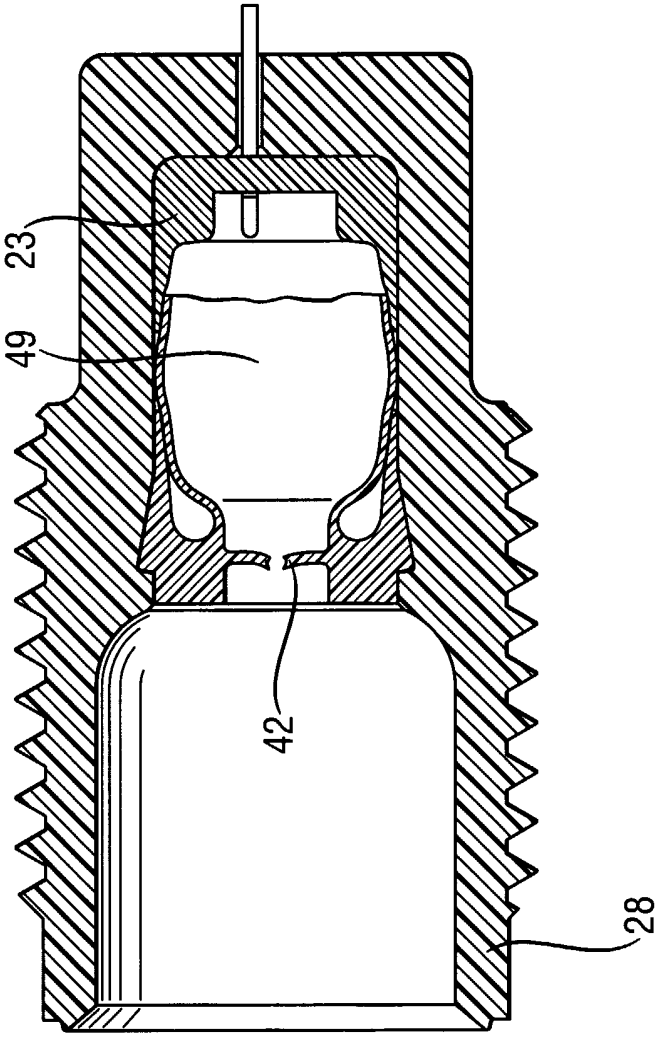


Fig. 7b

Fig. 8

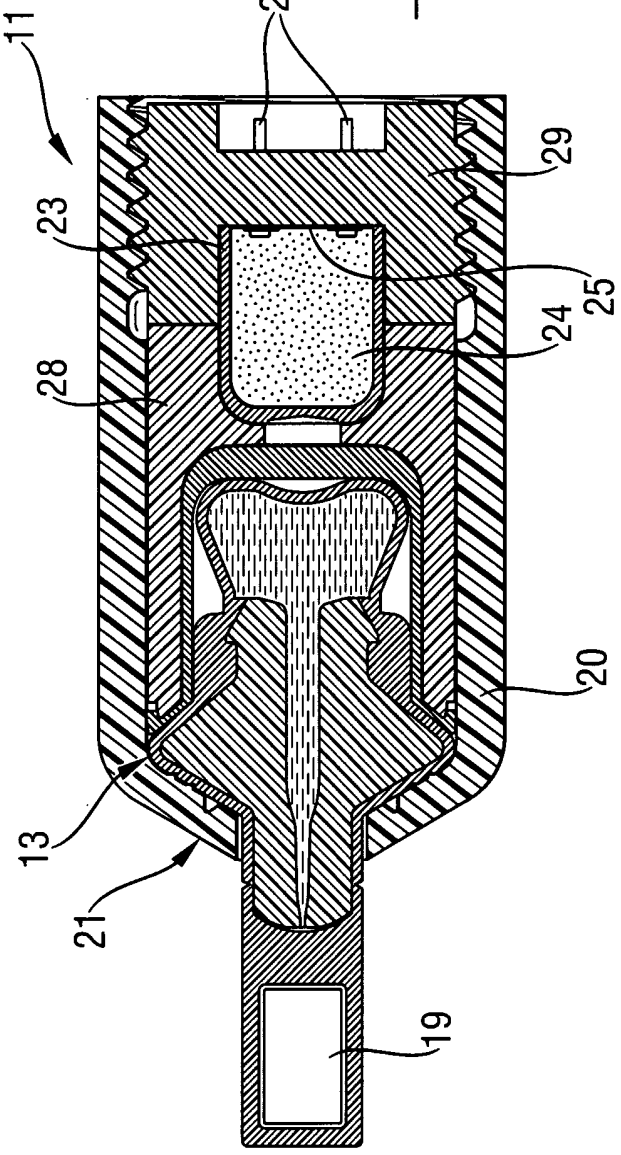
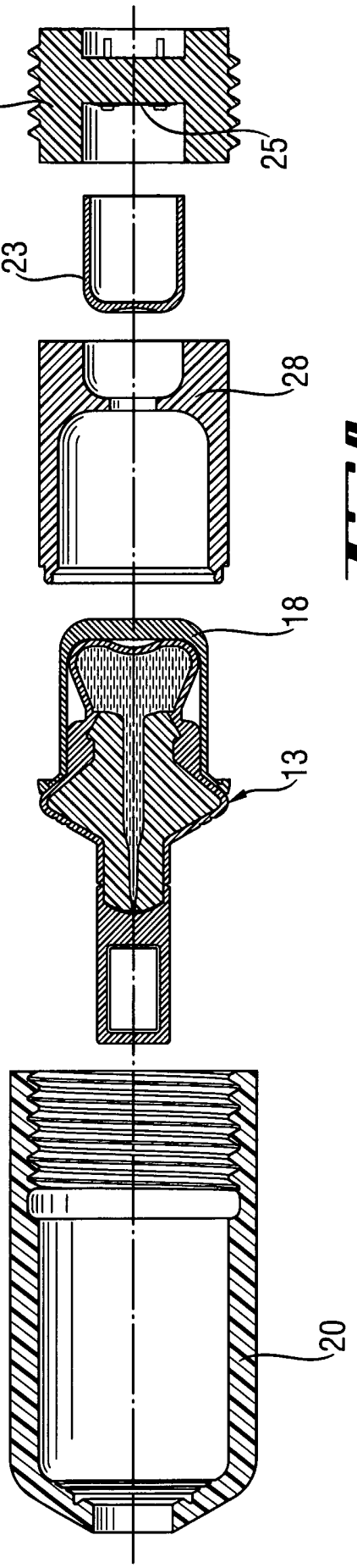


Fig. 9



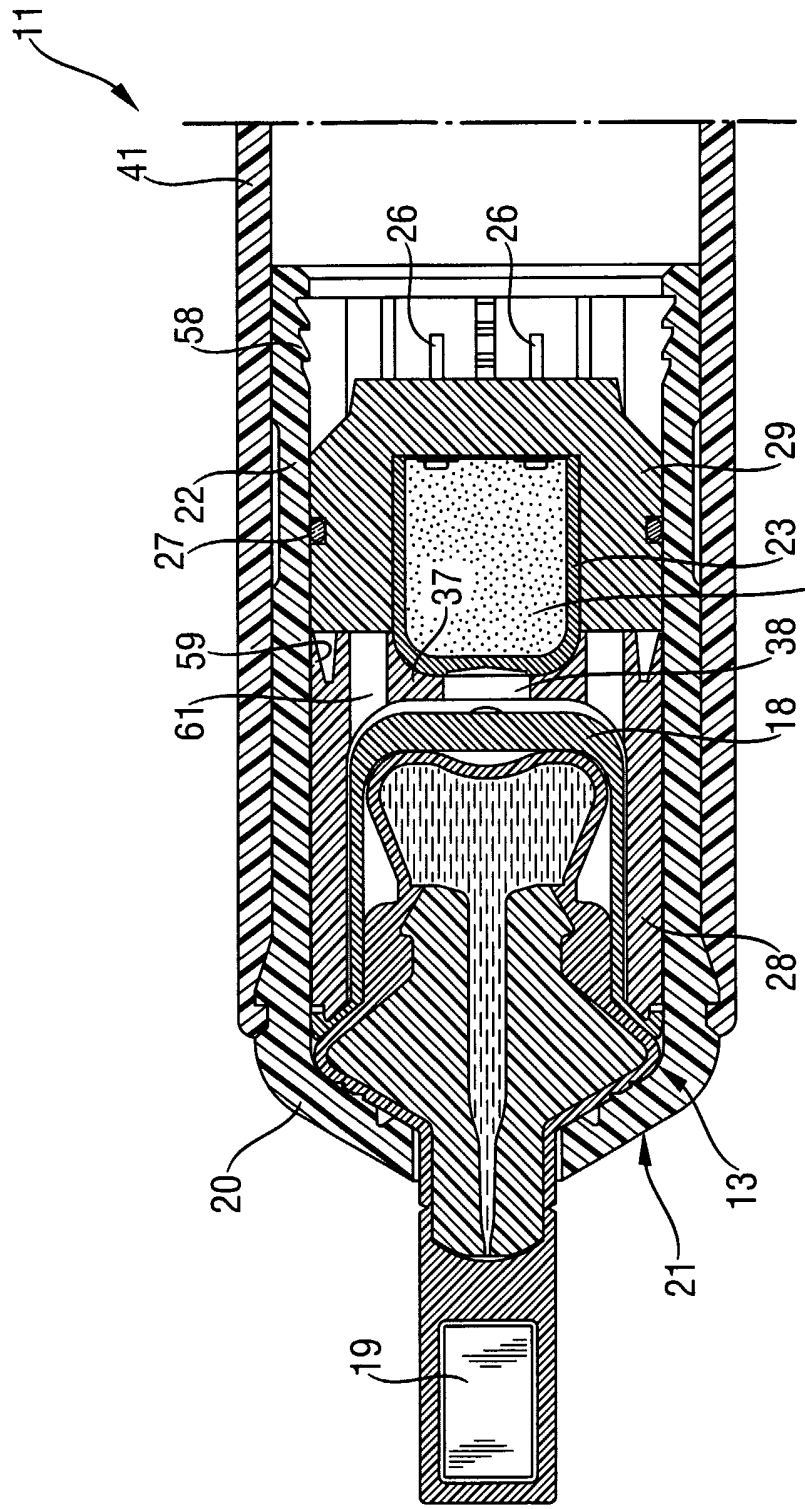


Fig. 10a

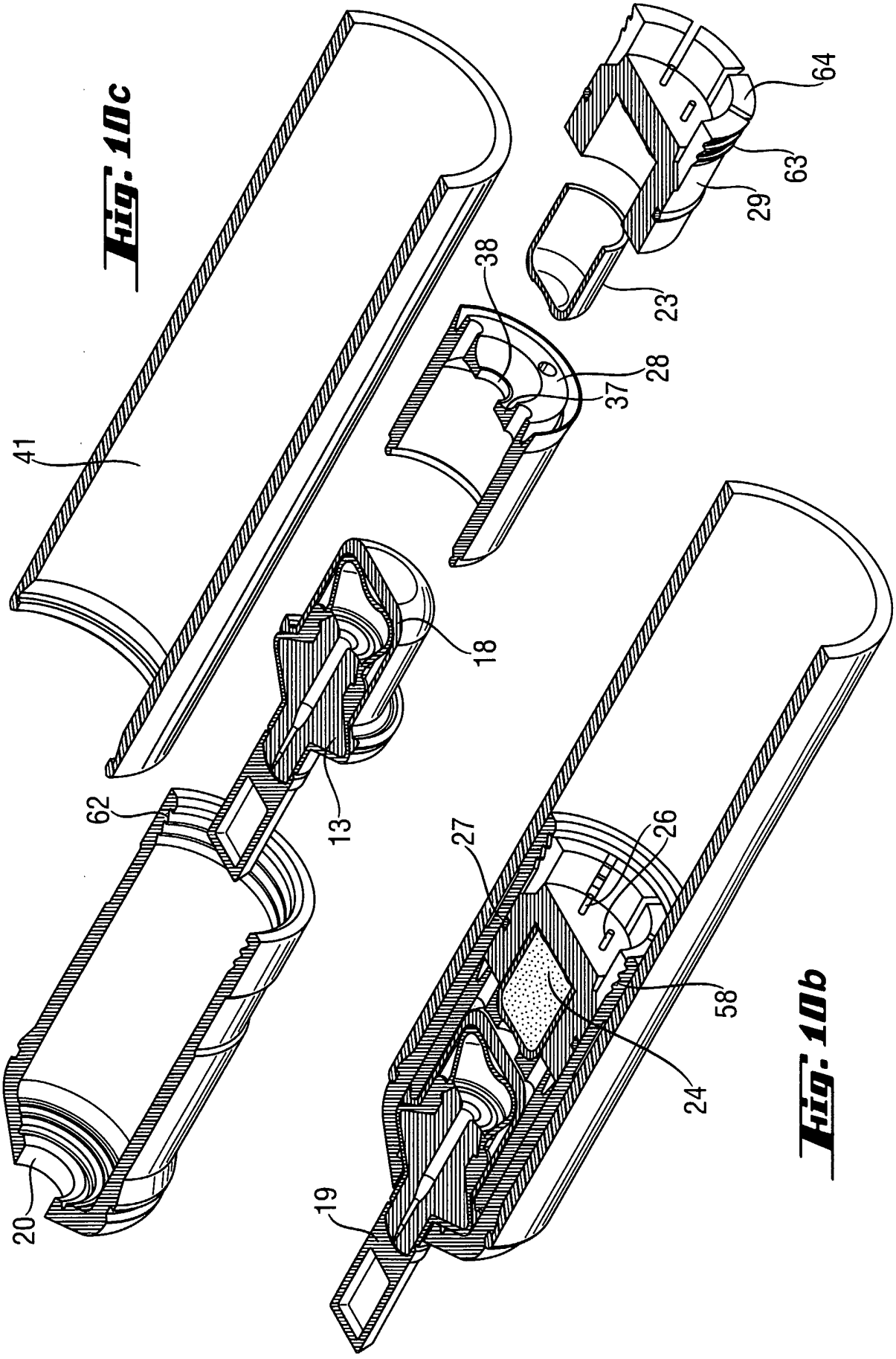


Fig. 10c

Fig. 10b

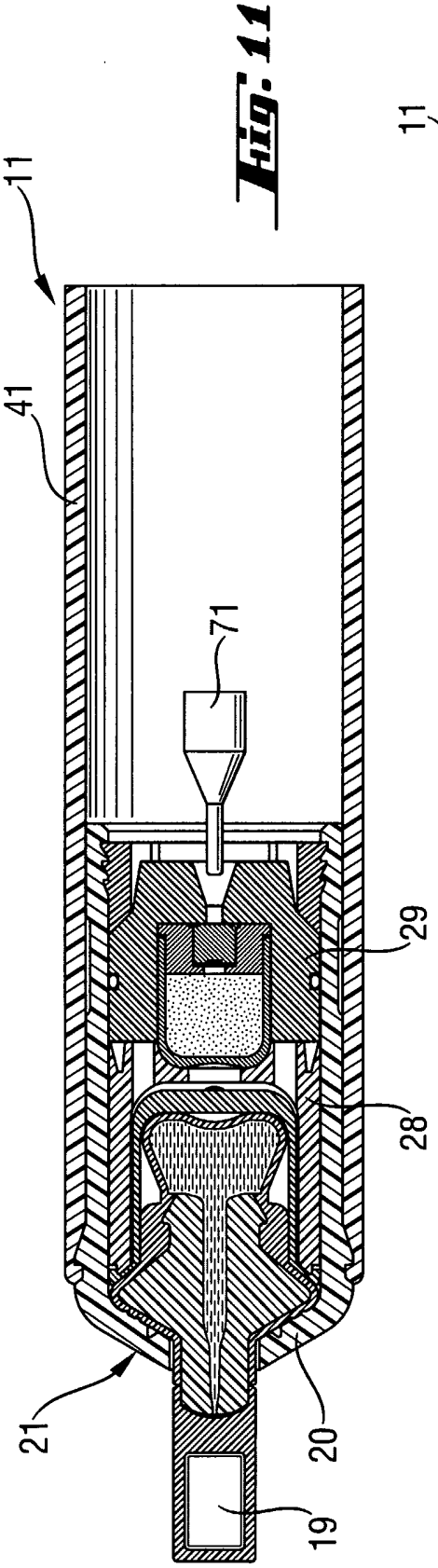

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Fig. 11

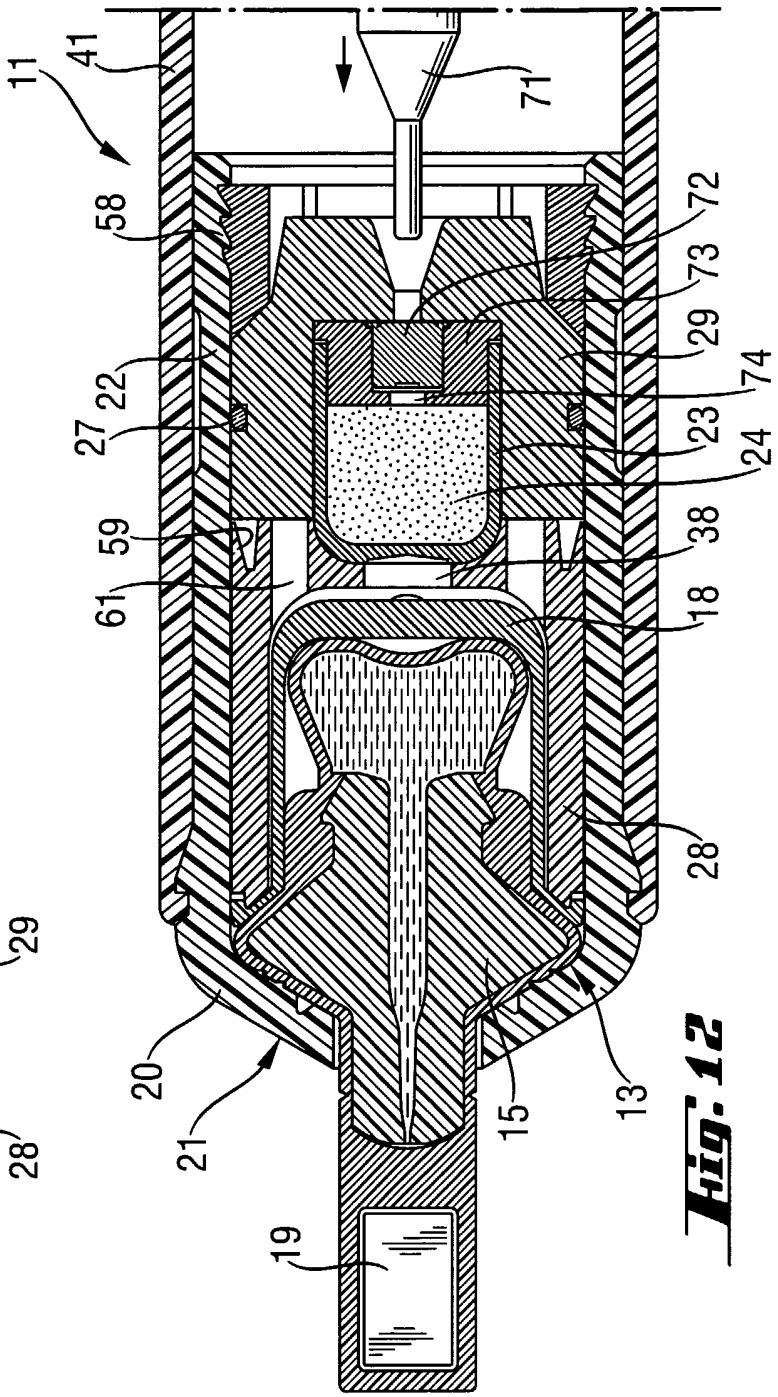
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Fig. 12

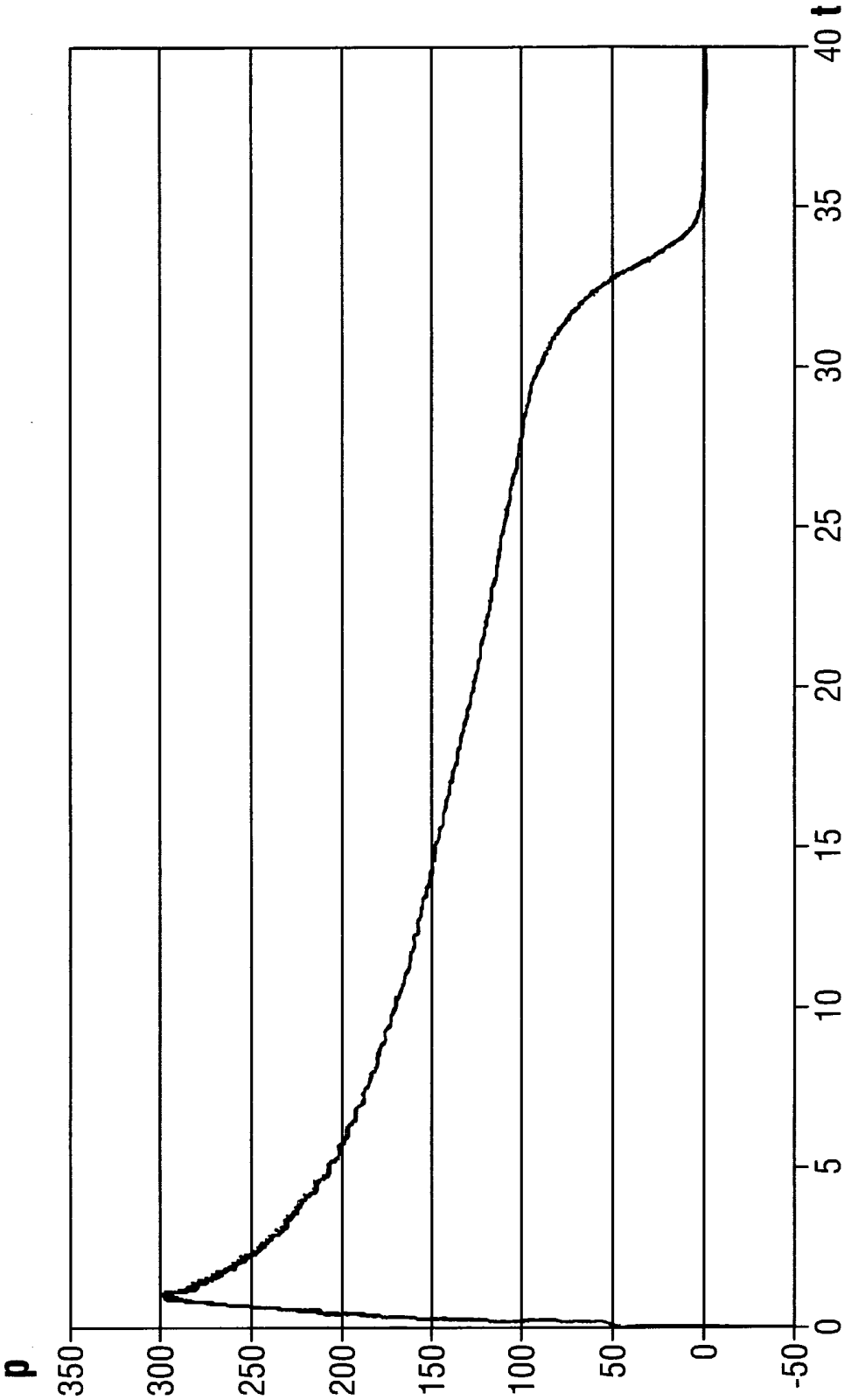

Fig. 13

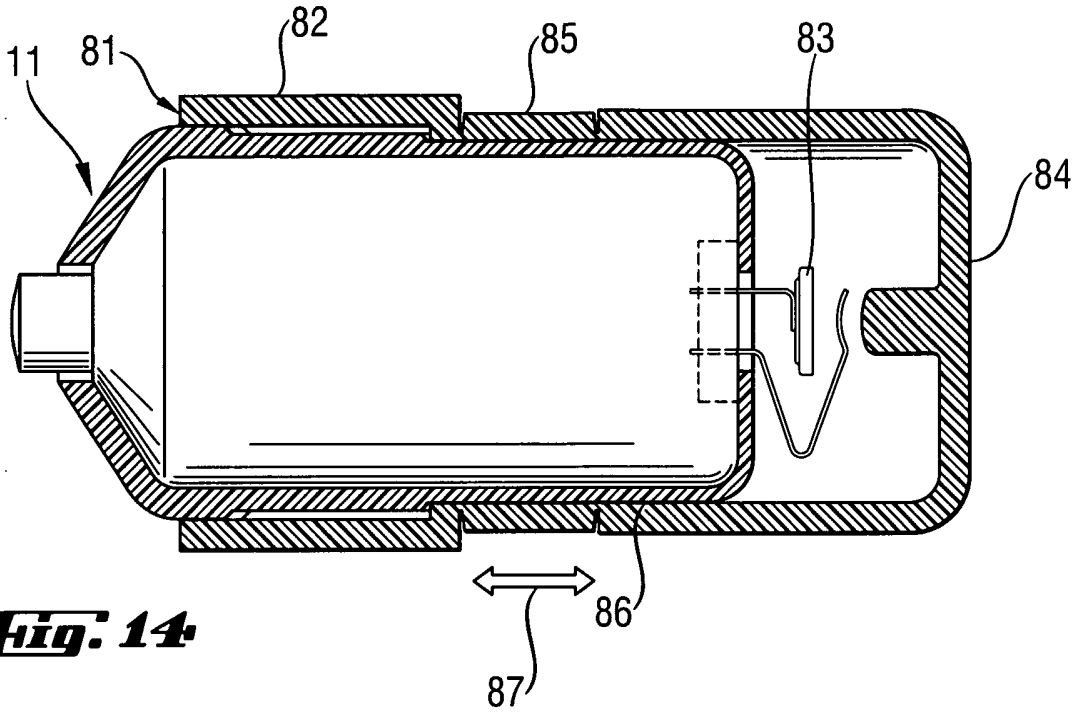

Fig. 14

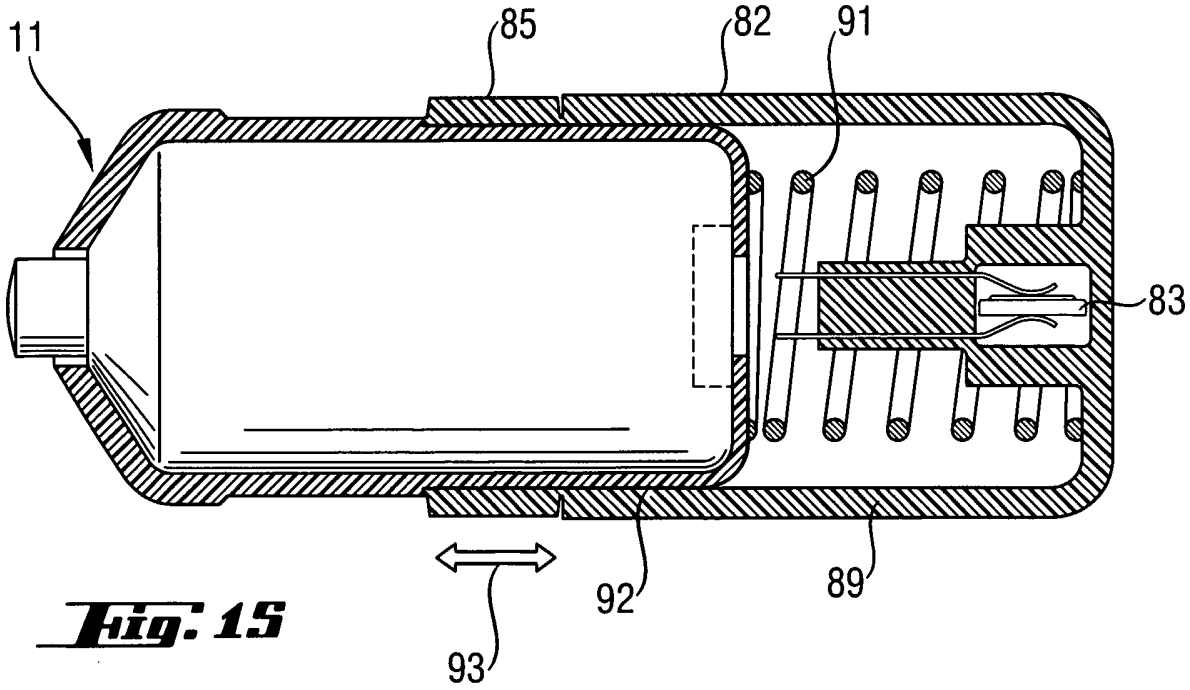

Fig. 15

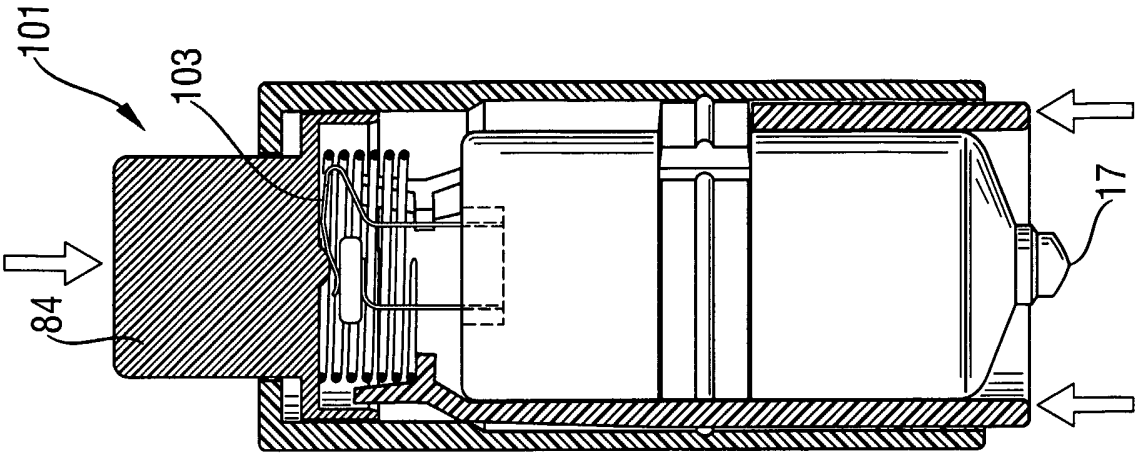

Fig. 16c

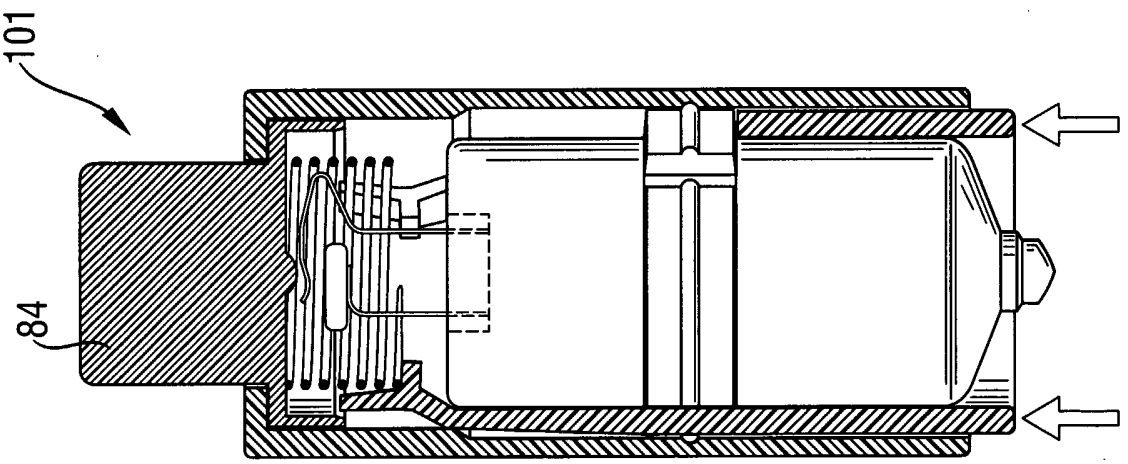

Fig. 16b

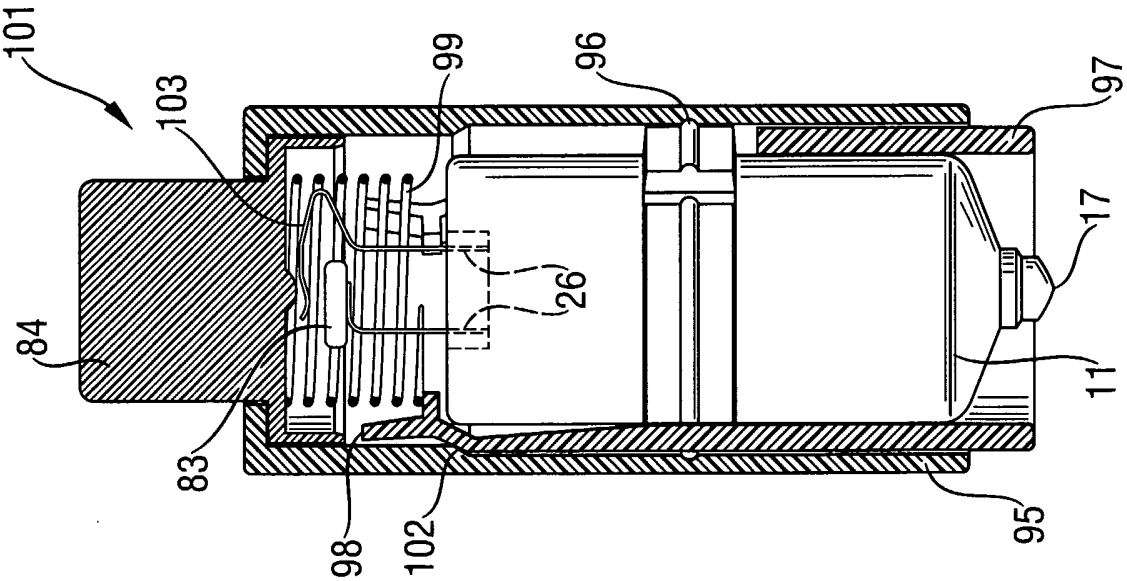

Fig. 16a

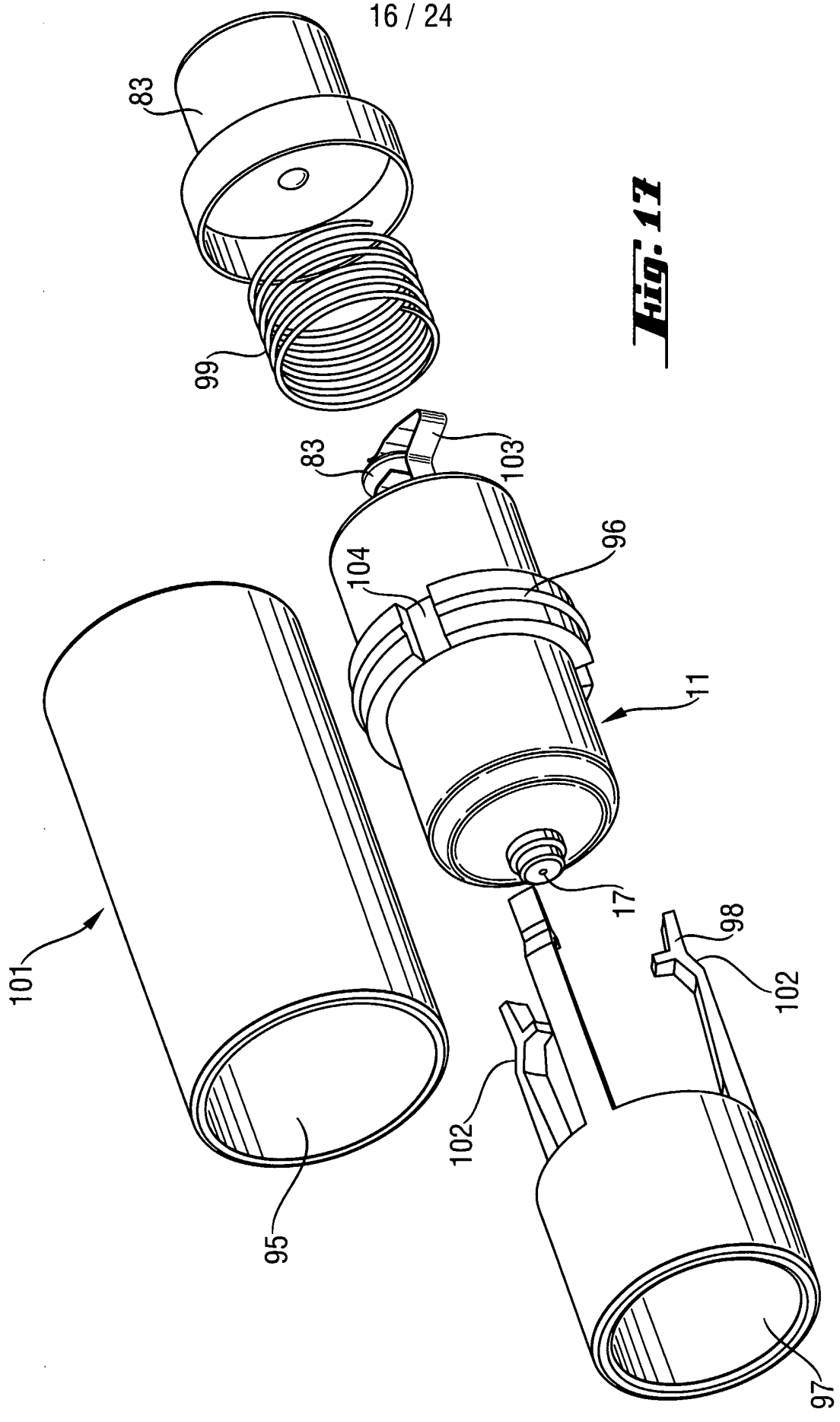

Fig. 17

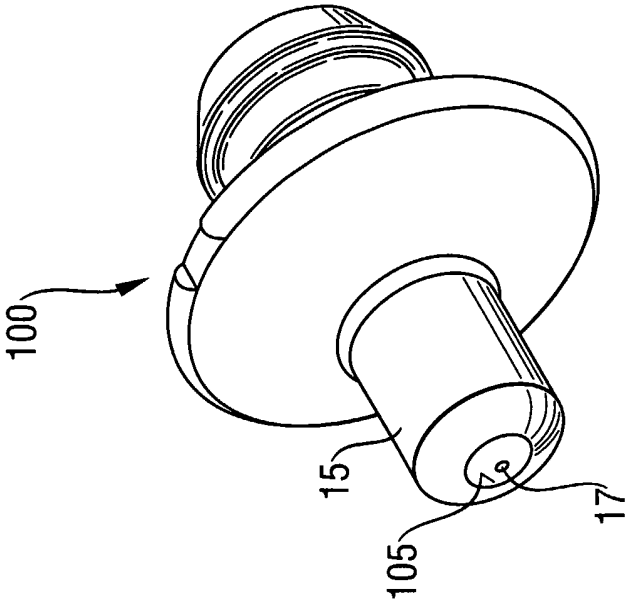

Fig. 18c

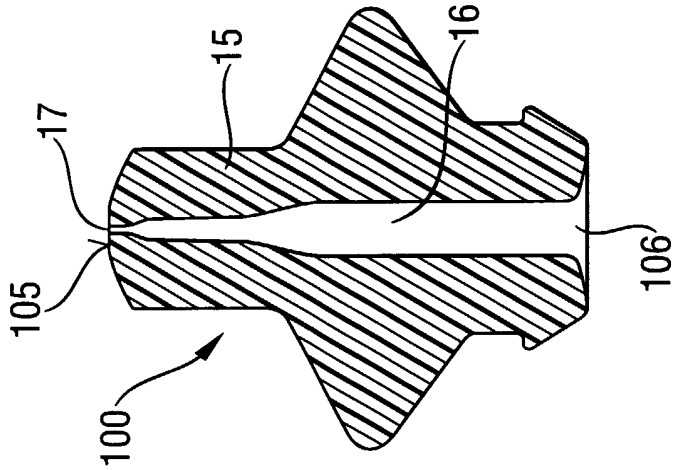

Fig. 18b

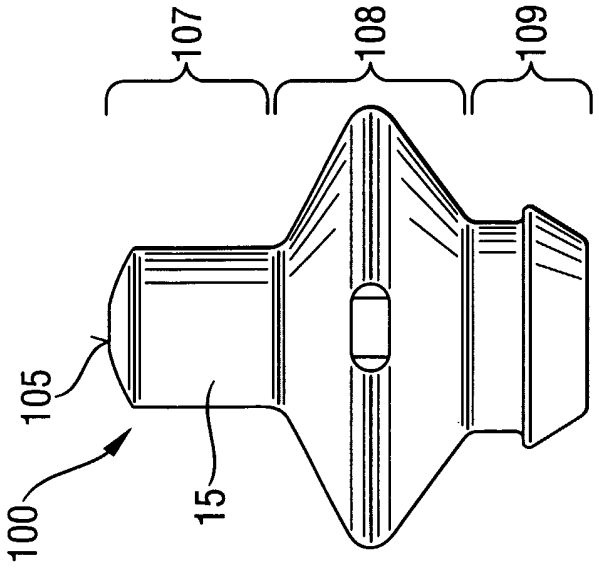

Fig. 18a

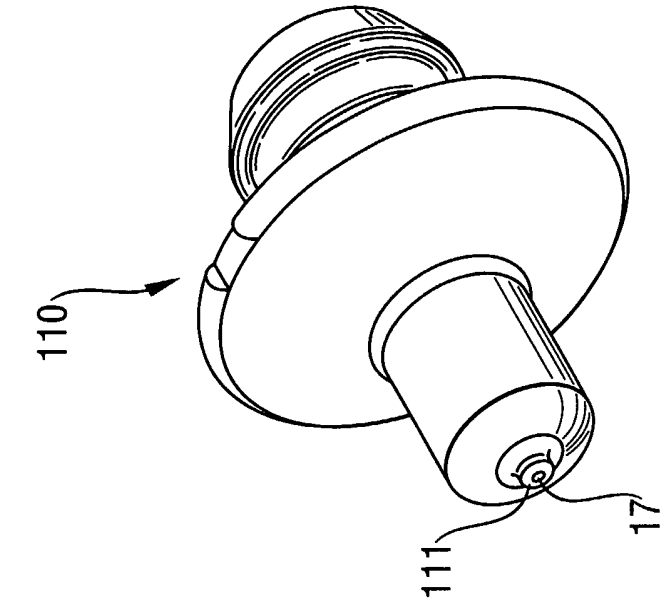

Fig. 19c

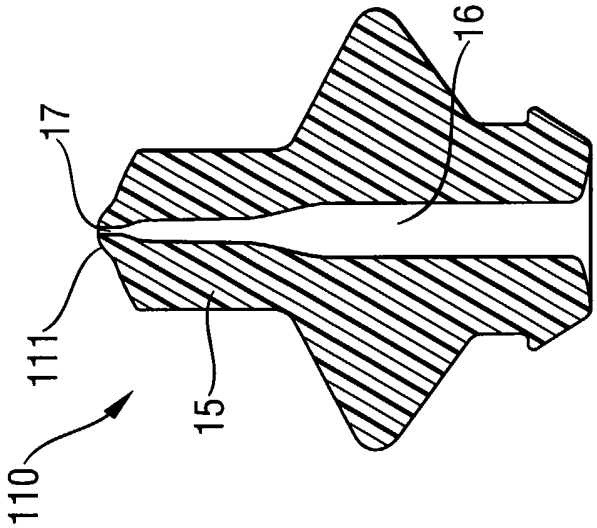

Fig. 19b

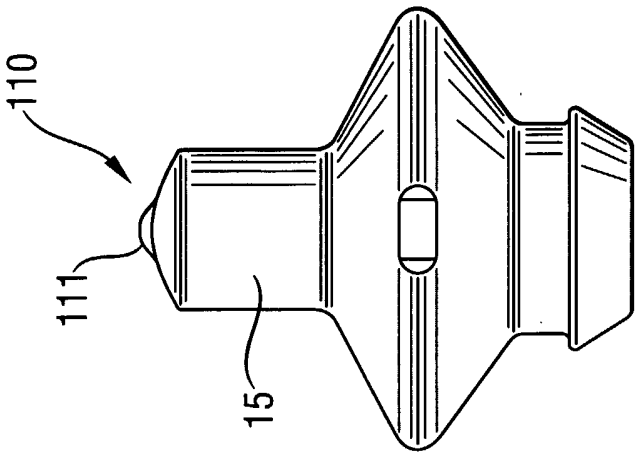

Fig. 19a

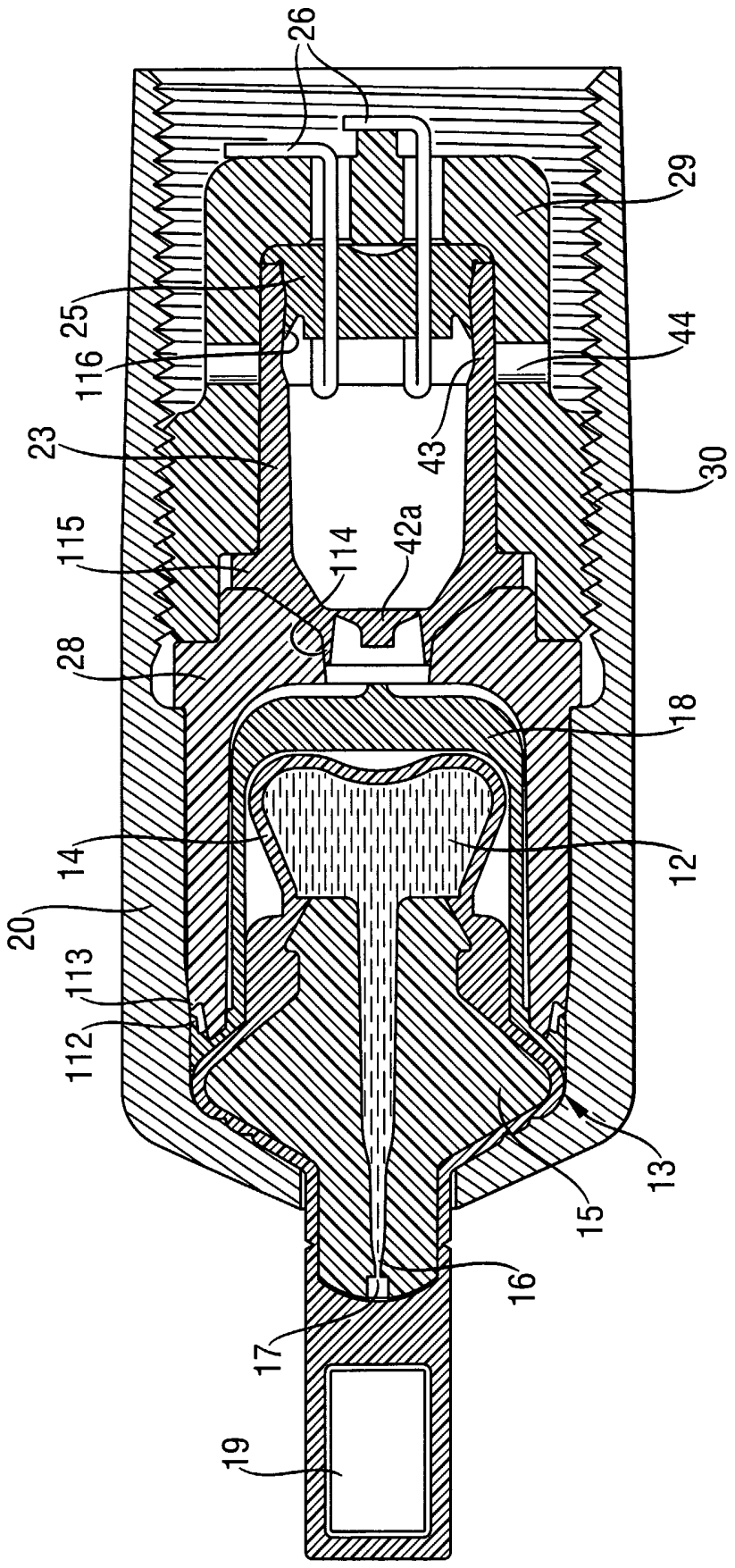
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Fig. 20

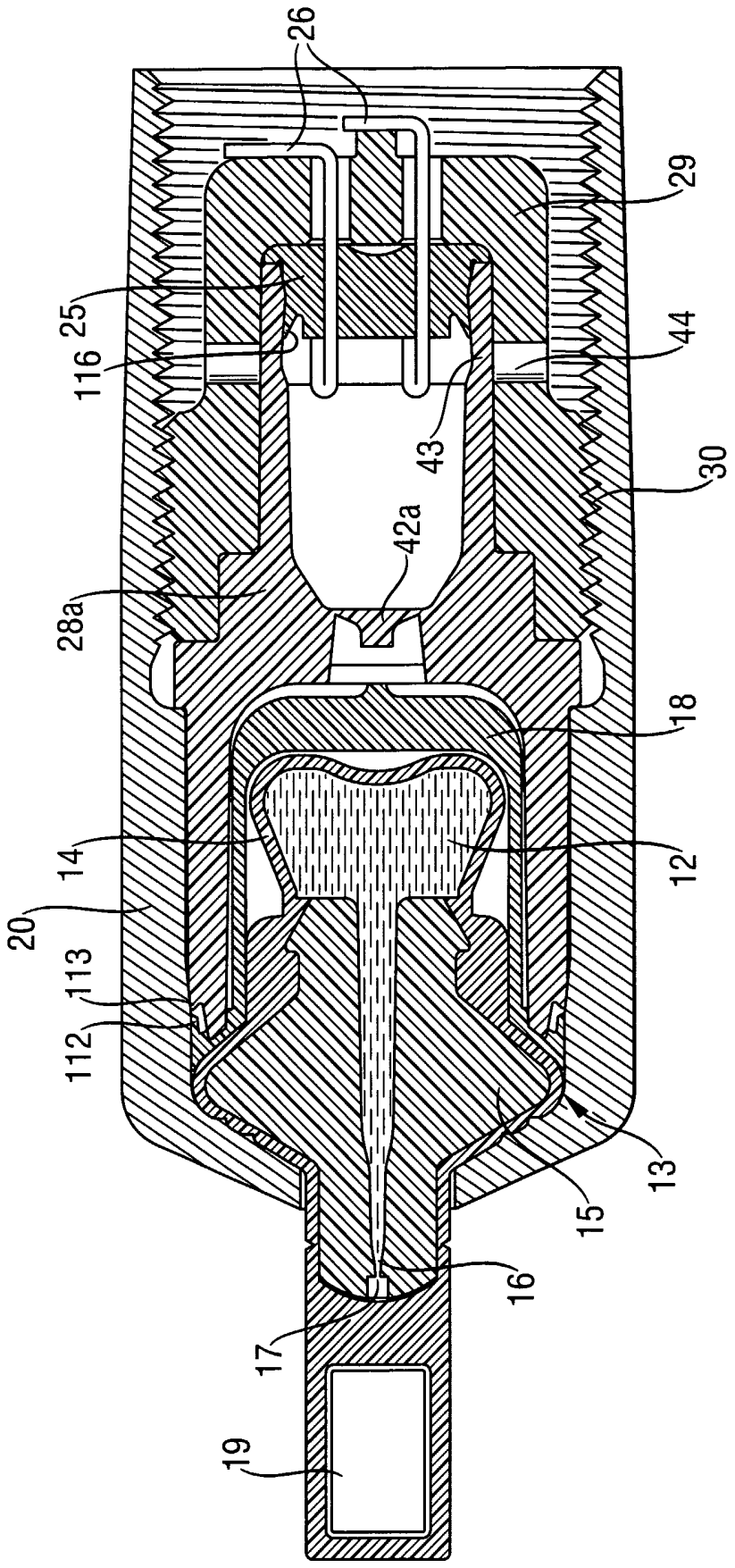

Fig. 21

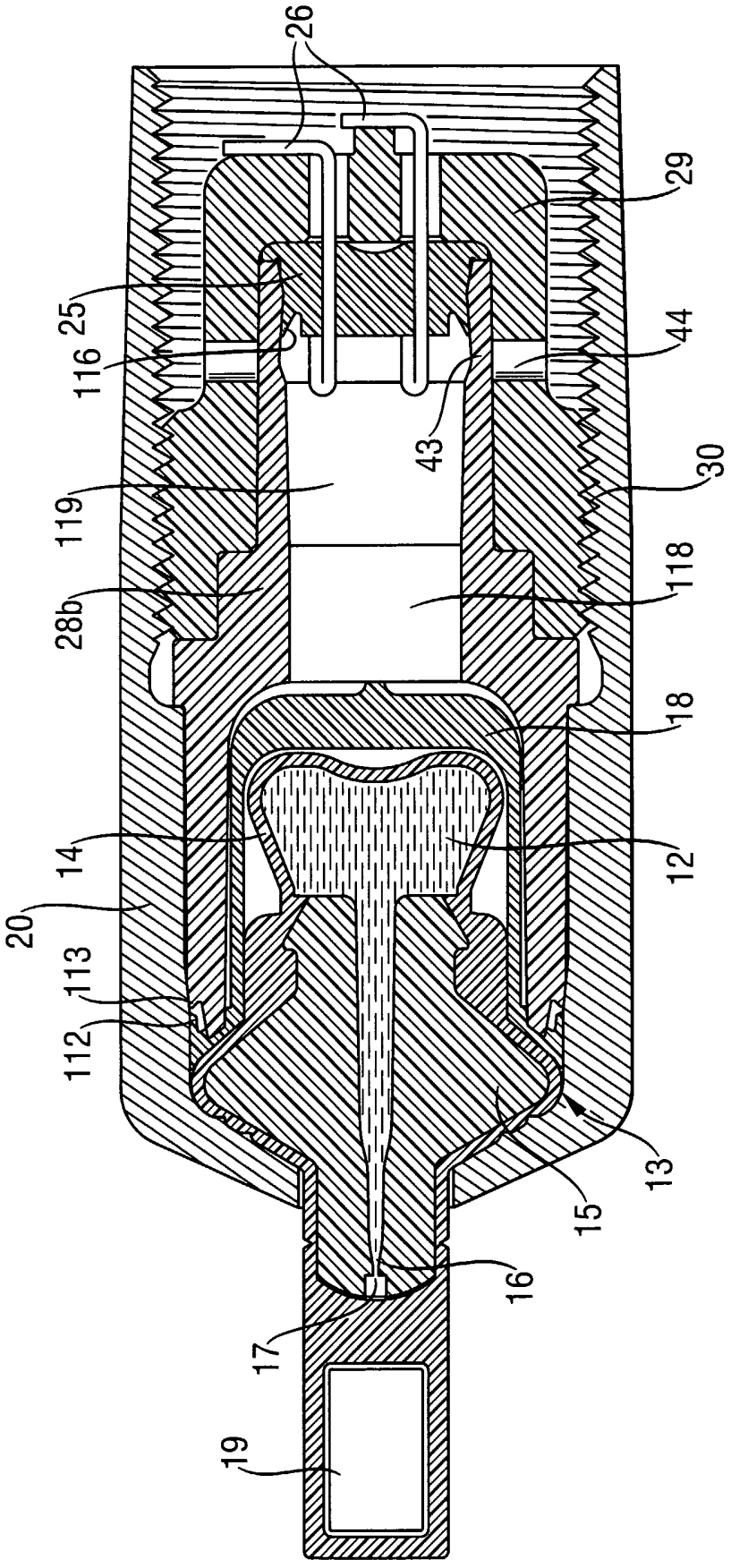

Fig. 22

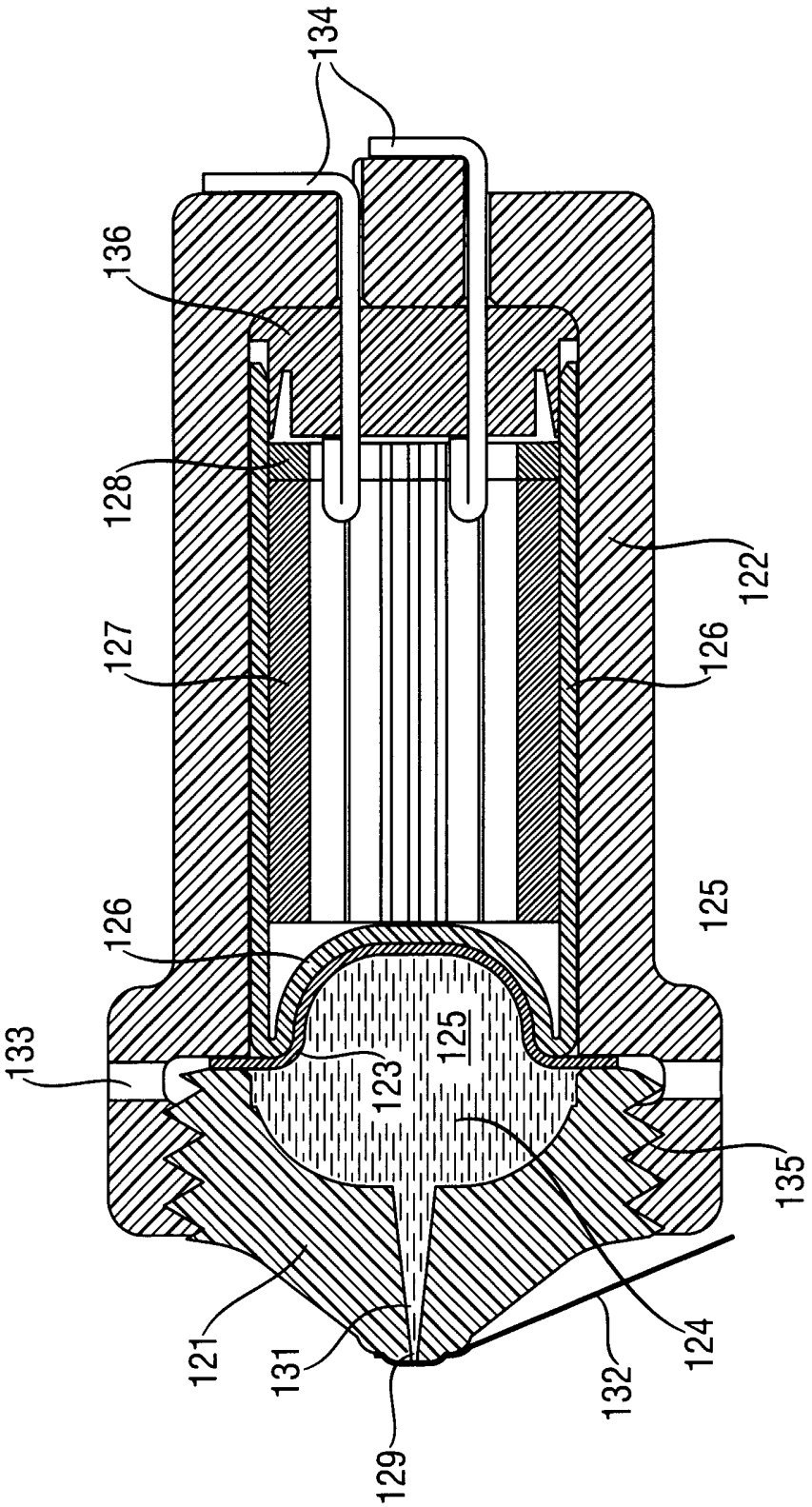
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Fig. 23

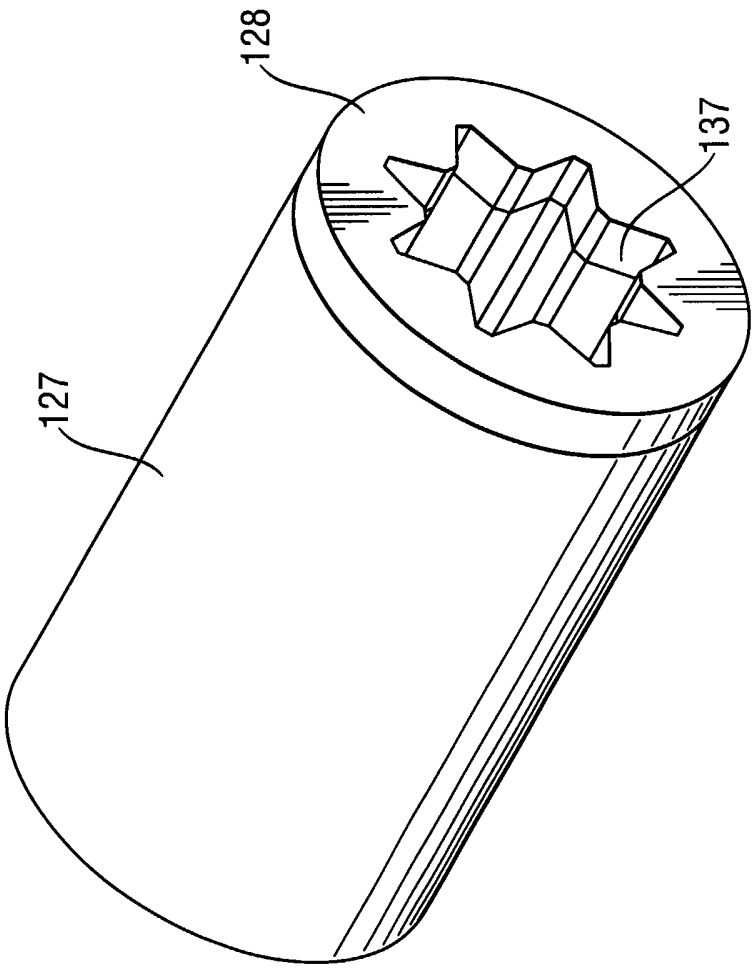

Fig. 24

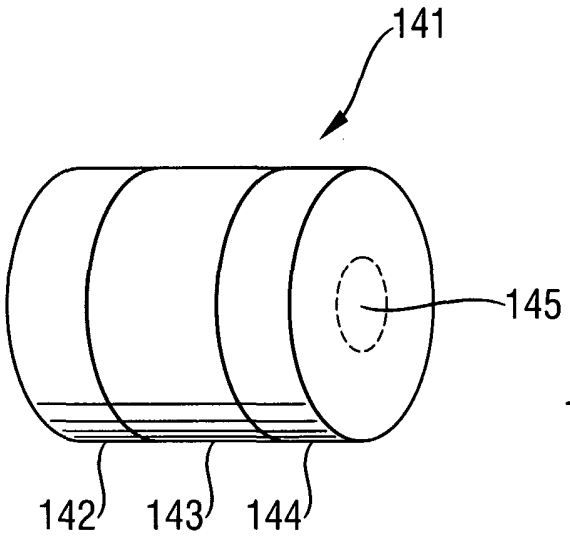

Fig. 25

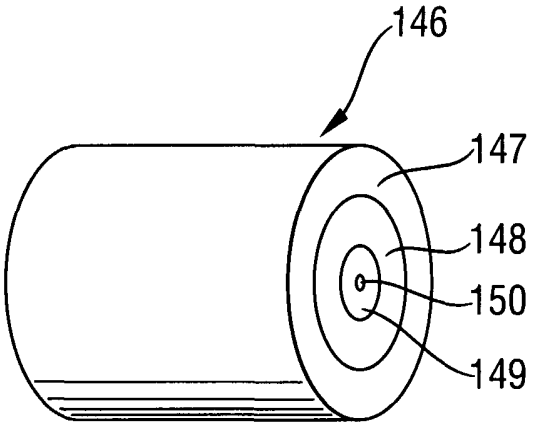

Fig. 26

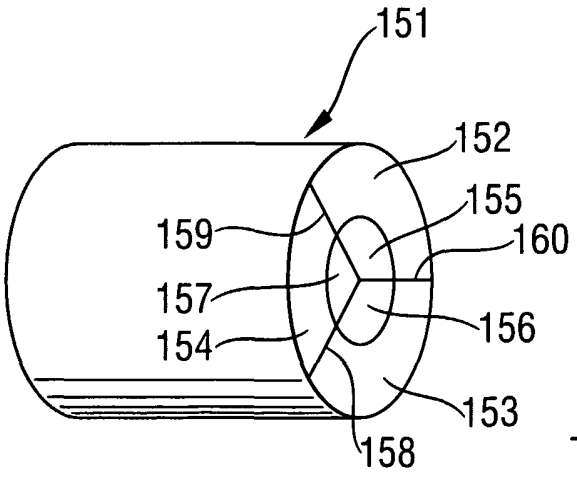

Fig. 27

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/13756

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/30 A61M5/20 A61M5/24 A61M5/48 A61M5/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 258 063 B1 (HAAR HANS-PETER ET AL) 10 July 2001 (2001-07-10) column 8, line 30 - line 33 column 11, line 29 - line 41 column 11, line 60 - line 66 column 12, line 55 - line 65 column 13, line 37 - line 60 column 14, line 28 - line 39 column 14, line 48 - line 50 column 17, line 9 - line 26 column 19, line 20 - line 21 figures 7,10	1,3-6, 11,12, 30, 35-37, 45,46, 54-56
A		2,7,13, 47,51, 61,67

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
10 April 2003	17/04/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Sedy, R

INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 99 48546 A (ELAN CORP PLC ;YAGIL GIL (IL); CARMEL EHOUD (IL); GROSS JOSEPH (IL) 30 September 1999 (1999-09-30) page 6, line 27 - line 33	8
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